

Comparison Of Topical Anaesthetic Spray Versus Oral Analgesics For Office Based Gynaecological Procedures – A Prospective Randomized Trial

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Abstract

Topical use of lidocaine is more effective than oral Ibuprofenat reducing pain during office-based gynaecological procedures. Additionally, a topical spray increases overall patient satisfaction with pain control during procedure.

INTRODUCTION:

Throughout history, mankind had tried to conquer pain. For office-based gynecological procedures, this is a challenge in view of the fact that post procedure patient monitoring may not be optimal. This precludes use of potent agents and opioids. Patient anxiety is another concern with office procedures. Options for pain control for these procedures range from oral analgesics, local anaesthesia or intravenous sedation. Procedures like intrauterine device (IUD) insertion, endometrial biopsy or aspiration, colposcopy and directed biopsy, hystero-salpingography and office hysteroscopy are routinely conducted in office setting. The modality for providing analgesia for these procedures is still unclear. Notwithstanding the popularity and frequency of all these procedures, there are no standard guidelines for anaesthesia, so the same procedures are being performed under general, local or no anaesthesia, depending upon the provider's choice.

This study was planned to assess analgesic effect of topical Lidocaine spray and oral analgesics during minor gynaecological procedures.

METHODS:

Present study was a randomized double - blind control trial conducted in the minor operation theatre, Department of Obstetrics and Gynaecology of a tertiary care centre of Eastern India catering to semi-urban population.

The study is approved by Institute's Ethics committee and registered in Clinical trial registry of India. Trial registry no. is CTRI/2017/09/009737

Aim of the study was to evaluate the efficacy of topical Lidocaine spray to decrease pain during office gynaecological procedures and to compare the pain scores with use of topical anaesthetic spray to that of standard oral analgesic and also to compare patient satisfaction in both the groups.

Sample size:

Power analysis for an independent sample t-test using the data for a pilot study done on 20 patients initially, was conducted in G-POWER to determine a sufficient sample size using an alpha of 0.05, a power of 0.80, a medium effect size ($d = 0.5$), and two tails (Faul et al., 2013). There was equal allocation of participants into each group. Based on the aforementioned assumptions, the desired sample size was calculated as 128.

Patient selection:

All patient attending the Gynaecological outpatient department and planned for office procedures mentioned below are evaluated and amongst them who are fulfilling the inclusion criteria are included in the study after explaining the procedure and taking informed and written consent.

Procedures included for the study were those, which require

visualization of cervix, tenaculum placement and entering into uterine cavity by a small diameter instrument. The procedure must not be requiring undue stretching, manipulation or dilatation of cervix. Procedures included are intrauterine contraceptive device (IUD) insertion, endometrial aspiration, endometrial biopsy (using pipelle canula or Karman's canula no.4), Hystero-salpingography (HSG), and office hysteroscopy using 2.9 mm hysteroscope.

Inclusion criteria were patient within age group of 18 to 50 years without any medical co-morbidity. As an institute protocol, pre-anaesthetic check-up was done by an anaesthetist for every patient and only patients belong to ASA-1 category were included in the study.

Exclusion criteria are any medical co-morbidity, patients belonging ASA -2 or more, known hypersensitivity to local anaesthetic agent or unwilling to participate in the study.

Patients who are fulfilling the inclusion criteria and had consented to be a part of the study were enrolled.

After a written informed consent and explaining the procedure, patients were randomly assigned into two groups using a computer generated program. Concealment was done using sealed envelope; similar in every aspect, sequentially numbered and containing computer-generated number sequence inside. The seal was opened and based on the randomization, intervention for pain reduction was given by investigator not performing the procedure. One group received tab Ibuprofen 400 mg orally half an hour prior to procedure (group- A, n=64)and the other group was given 10% Lidocaine spray 4 puffs (10 mg each puff) locally over cervix and upper vagina after placing a sim's speculum, five minutes prior to procedure(group- B, n= 58).

For placebo effect, group-A Received Saline spray with identical technique and group- B received oral calcium tablet.

All procedures are carried out by the same gynaecologist and analgesia was provided by another investigator, operator being not knowing about what was administered for pain relief to a particular patient.

PAIN ASSESSMENT:

As all participants were fully awake during the procedure, at the completion of the procedure, all patients were asked about the degree of pain they perceived while undergoing the procedure. To assess the pain perceived, a 10 point

numeric rating scale (NRS) was used.

All patients were also analyzed for their satisfaction level at a scale of 1- 100, the same scale was validated prior to the study in 20 patients

Pain and satisfaction assessment was done by the investigator who does not know their allocation group.

Primary outcome was pain during procedure and secondary outcome was patient's satisfaction.

RESULTS:

During the study period, total 138 procedures under defined criteria were performed by the investigator. Participants flow has been described in fig.1.

64 patients were enrolled in oral analgesic group and 58 patients were enrolled in local lidocaine spray group. 16 patients where negotiation through internal os was found to be difficult were excluded from the study. All patients received the intervention to which they are allocated and no one was lost to follow- up.

Data was analysed using spss software version 22.0

On applying One- sample Kolmogorov – Smirnov test, data distribution was found to be normal, hence, mean were compared and independent t – test were applied as applicable.

The two comparison groups were similar in demographic and peri-operative characteristics (Table-1).

Table 1

Demographic profile of patients in two groups

Characteristic	Group-A (oral Ibuprofen) n= 64	Group-B (lidocaine spray) N=58
Age (yrs)	37.45 ±10.245	36.52±10.224
BMI (Kg/m ²)	26.1 (18.7- 34.5)	26.5 (17.9 – 36.2)
Education		
Illiterate	14 (21.87%)	11 (18.94%)
Literate	10 (15.63%)	12 (20.68%)
High school	06 (9.4%)	08 (13.79%)
Intermediate	16 (25%)	12 (20.68%)
Graduate and above	18 (28.1%)	15 (25.93%)

BMI, body mass index.

Data are mean, ± SD, n (%) or (range)

The mean age of our study population was 37.01 years. Both groups were comparable with respect to age, body mass index and education and no statistically significant

difference was noted.

For the primary outcome, pain during the procedure, women who received local spray of lidocaine to cervix and upper vagina reported significantly lower levels of pain than women in the oral analgesic group with mean score 3.55 in comparison to 5.81 in oral analgesic group with 95% confidence interval of the difference is 1.71 – 2.811 and p value .000 by using independent t – test. (Table – 2)

Table 2

Comparison of pain scores for the oral Ibuprofen and topical Lidocaine spray

Group	N	Mean ±SD	95% CI of the difference	p- value
Group – A (oral Ibuprofen)	64	5.81 ±1.622	1.71 – 2.811	.000
±Group – B (topical lidocaine spray)	58	3.55 ± 1.429		

Mean satisfaction was 41.88 on a scale of 100 in oral Ibuprofen group, while it was 70.60 in topical lidocaine spray group. P value is highly significant using independent t – test. (Table – 3)

Table 3

Comparison of Satisfaction scores for the oral Ibuprofen and topical Lidocaine spray

Group	N	Mean± SD	95% CI	p- value
Group – A (oral Ibuprofen)	64	41.88 ± 15.824		<.001
Group – B (topical lidocaine spray)	58	70.60 ± 13.314	-34.000 to -23.457	

In addition, there were no reported major side effects during the study, except slight nausea in four patients in oral analgesics group and local burning sensation following spray in three patients.

DISCUSSION:

Office gynaecological procedures are commonly done for women across all age groups, particularly during their reproductive ages. In reality, most of the women, given appropriate counselling and pain management, tolerate these procedures well in outpatient setting. Office procedures do have many advantages and increase patient and provider's convenience. However, to achieve this, patient selection and attention to patient comfort are important factors.

For pain relief during gynaecological procedures, usual options include oral analgesics, para cervical block or intravenous sedation. Here we evaluated the usefulness of topical lidocaine spray for control of pain during office gynaecological procedures.

Patient selection is very important aspect for office procedures. Candidates should be healthy and free from co-morbidities. In the present study, we have included patient belonging to American society of anaesthesiologists physical status classification system category I only.^{1,2} In addition, all patients were explained about what is going to be happen with them during this procedure and anticipated pain, we have found that counselling of the patient explaining what is going to happen next decrease patients anxiety to a significant level.^{3,4,5}

A paracervical block with Lidocaine is commonly used for analgesia in most gynaecological procedure and is found to be effective in various studies^{6,7} and is time tested but it is usually required for procedures which are time taking and which needs cervical dilatation or manipulation as cervix has maximum pain during stretching. But while choosing to administer local anaesthetic, the risks associated, allergic reaction and intravasation of anaesthetic must also be considered. Moreover, para-cervical administration of anaesthesia is a painful procedure. Therefore, for shorter duration office procedure where minimum cervical manipulation is anticipated, clinicians usually prefer oral analgesics over para-cervical block because of the complexity and pain involved in the later. For these short duration procedures, we usually prescribe NSAIDs half hour prior to procedure but is not found to be very effective for pain control.

Hubacher et al. did not find any significant pain relief with 400 mg Ibuprofen where comparing to placebo in their randomized control trial.⁸ Multiple studies are available in literature for use of NSAIDs or cervical ripening prior to IUD insertion, but those studies were having their own limitation and did not find any significant improvement in pain score.^{9,10,11}

¹²Danielsson et al while evaluating for management of pain during IUD insertion in their meta - analysis, concluded that no prophylactic pharmacological intervention has been adequately evaluated to support routine use for pain reduction during or after IUD insertion.

The search for an acceptable anaesthetic agent which alleviates the pain, but at the same time, administration of such anaesthetic should not be more painful than the procedure itself, ends at topical anaesthetic agents which are available in the form of cream, gel and spray. Topical anaesthesia have routinely been used for skin, eye, ear, nasal mucosa, oral and broncho-tracheal area, and even for endoscopy, but very less explored for use in female genital tract. As we know, pain during procedures involving female genital tract, is due to manipulation of cervix and uterus. Sympathetic fibres from T10 to L2 innervates uterine fundus, parasympathetic fibres from S2 to S4 enters the cervix at 3 and 9 O'clock position and innervates lower uterine segment, cervix and upper vagina. Lower vagina and vulva are supplied by Pudendal nerve (S2,3,4)¹³. All types of Lidocaine preparations acts by stabilizing the neuronal membrane by inhibiting ionic flow and are effective when applied locally.

Lidocaine is available as 10% solution in the form of spray, maximum adult dose being 400 mg and is widely and effectively being used for topical anaesthesia for accessible mucous membranes of oral and nasal cavities and proximal portions of digestive tracts during endoscopy in non-sedated patients.^{14,15} Topical lidocaine preparations are reported to be very safe, levels greater than 5 mcg/ml are reported with toxicity, mainly visual disturbances in lower levels, while CNS side-effects are associated with very high levels.¹⁶ Topical lidocaine is contraindicated in patients with hypersensitivity to local anaesthetics.

Many studies have evaluated use of intrauterine anaesthesia using lidocaine for gynaecological procedures with good efficacy.^{17,18}

Researchers have evaluated the use of Lidocaine spray in IUD insertion with good efficacy, though we could not find much literature on its use in other Gynaecological procedures apart from IUD insertion.

McNicolas et al evaluated use of topical Lidocaine gel vs placebo for IUD insertion and did not find any significant difference in pain.¹⁹ 10% lidocaine spray was used topically to reduce pain during IUD insertion in placebo controlled randomized control trial by Aksoy²⁰ with significant results. Torkey et al.²¹ found lidocaine spray more effective than lidocaine gel for pain reduction during cervical traction in the procedure of IUD insertion.

Yetkin Karasu et al found lidocaine spray more effective for pain reduction than gel and paracervical injection both²².

A recent Cochrane review for the same was done in 2015 and concluded that lidocaine gel, NSAIDs and misoprostol did not help in reducing pain while lidocaine spray, tramadol and Naproxen were of some help.²³

In this study, we found that lidocaine spray significantly improves pain and patient satisfaction during minor gynaecological procedure over NSAIDs. The main factor for pain relief could be not feeling any pain of drug application and tenaculum placement. Cervix mainly responds to stretching and procedures involving stretching and dilatation of cervix are found to be more painful. Hence, the cases selected for the study are the one where cervical dilatations are not required, if in any patient, negotiating the cervical os is found to be difficult, that case is eliminated from the study. Additionally, lidocaine spray is available in a pump valve container which makes the application very easy. Additionally, in a country like India, where cost factor plays major role in treatment, lidocaine spray can be very useful because of its low cost.

CONCLUSION:

Present study demonstrated that lidocaine spray is an easy, rapid and safe method of pain control during minor gynaecological procedures and is proved better than NSAIDs for the same. Since, administration of paracervical block is painful, rather more painful than the procedure executed at times, hence, is not a good choice for minor procedures. We recommend that topical lidocaine spray should be used more frequently for anaesthesia during minor gynaecological procedures to decrease the pain effectively.

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