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ORIGINAL ARTICLE

Comparison of Local Anesthesia and Analgesic Effects of Piroxicam in Aspiration Curettage

Akın Dayan, Emine Zeynep Tuzcular Vural

Department of Family Medicine, University of Health Sciences Türkiye, Haydarpaşa Numune Training and Research Hospital, Istanbul, Türkiye

Abstract

Introduction: We aimed to investigate whether piroxicam, either alone or in combination with the local anaesthetic agent lidocaine hydrochloride, differs from standalone local anaesthesia and without medication, thereby providing effective pain control in the termination of early pregnancies.

Methods: Our study is a case-control study in which 177 individuals with pregnancies between 5-9 weeks of gestation who applied to the research hospital, Department of Obstetrics and Gynecology, for legal pregnancy termination were included. The participants were divided into four groups. The groups were administered as follows: a control group without medication, a paracervical block with lidocaine hydrochloride, sublingual piroxicam, and a combination of both lidocaine hydrochloride and sublingual piroxicam. After the completion of the aspiration curettage procedure, the pain intensity experienced by the groups was evaluated using the Five-Point Pain Scale.

Results: The participants' mean age was 31.02±6.14 years, and the average gestational week was 7.05±0.78. There was a statistically significant difference in pain intensity among the groups ($p<0.001$). The pain intensity in the control group was significantly higher than in the local anaesthetic ($p<0.001$), piroxicam ($p<0.001$), and piroxicam + local anaesthetic ($p<0.01$) groups.

Discussion and Conclusion: The use of lidocaine hydrochloride for paracervical block, in combination with piroxicam during the aspiration curettage procedure for pregnancies between 5-9 weeks, is effective, safe, and provides good pain control.

Keywords: Abortion; Legal; Local Anesthesia; Piroxicam.

United Nations Population Fund reports that approximately 121 million pregnancies worldwide, which accounts for nearly half of all pregnancies, are unintended[1]. Over 60% of unintended pregnancies result in abortion, and an estimated 45% of all abortions are unsafe. The mortality rates for safe abortions are less than 0.2%, while those for unsafe abortions range between 4.7% to 13.2%. This has a significant impact on the world's progress toward achieving the Sustainable Development Goals[1-3].

Complications and sequelae resulting from unsafe, primitive, or untrained-induced abortions are far more dangerous compared to pregnancy terminations carried out under controlled, healthy conditions. In countries where family planning methods and legal abortion are practiced under state supervision, serious and life-threatening complications can be largely prevented. Indeed, even when conducted by a physician under hospital conditions, pregnancy termination carries inherent risks. Therefore, it is essential for the methods used in the termination of

Correspondence: Akın Dayan, M.D. Department of Family Medicine, University of Health Sciences Türkiye, Haydarpaşa Numune Training and Research Hospital, Istanbul, Türkiye
Phone: +90 532 276 05 62 **E-mail:** akindayan@yahoo.com
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unwanted pregnancies to be effective, reliable, provide good pain control, and be economically viable. In this regard, medical methods have been used reliably and effectively as alternatives to surgical methods for early pregnancy termination since the 1960s, with procedures such as dilation and vacuum aspiration, and later in the 1970s with the use of prostaglandins and in the 1980s with the clinical availability of the progesterone receptor blocker mifepristone[4].

In the termination of early pregnancies, especially those up to 9 weeks of gestation, the aspiration curettage method performed under general anesthesia or sedation, combined with local anesthesia, is considered to be less complicated, painful, and more acceptable compared to medical abortion[5,6].

In many cases, the use of general anesthesia is not practical due to its elevated cost, increased morbidity, and mortality[7]. In the legal termination of early pregnancy and in cases of miscarriage, it has been demonstrated that vacuum aspiration under local anesthesia is equally safe and effective compared to the procedure being performed under general anesthesia. The procedure conducted under local anesthesia provides adequate pain control and results in high patient satisfaction[8]. Indeed, due to these findings, clinicians involved in pregnancy termination should explore options that provide better pain control.

In this study, our aim was to investigate whether the non-steroidal anti-inflammatory drug piroxicam, either alone or in combination with the local anesthetic agent lidocaine hydrochloride, exhibited superiority over standalone local anesthesia and the group without medication. The ultimate goal was to provide economical, reliable, and effective pain control in the termination of early pregnancies.

Materials and Methods

Our study is a case-control study, and a total of 177 individuals who presented to the two training and research hospitals, Haydarpaşa Numune and Zeynep Kamil Training and Research Hospitals, Departments of Obstetrics and Gynecology, requesting legal pregnancy termination, were included. The study received approval on August 29, 2023, and was assigned the reference number E-62977267-903.99-223958174. It was conducted in strict adherence to the principles outlined in the Declaration of Helsinki. In the clinic, we routinely administer oral analgesia and/or paracervical block. As a result, the control group patients were selected from another training and research hospital where this procedure was not performed. Apart from analgesia, aspiration curettage for the termination of early pregnancy was performed in the same manner according to the guidelines of Türkiye's Ministry of Health. All participants in the study were selected from among the outpatient cases with 5-9 weeks of gestation who sought care before pregnancy termination. The patients were given information about the study and provided informed consent. All patients underwent ultrasound and gynecologic examination for confirmation of gestational age.

The cases were divided into four distinct groups. The first group comprised 40 cases assigned to receive no medication. The second group, consisting of 48 cases, received a paracervical block with lidocaine hydrochloride (Jetocain amp, ADEKA®, Türkiye) only. The third group, which included 48 cases, received only sublingual 40 mg piroxicam (Felden Flash 20 mg, Pfizer®, USA). Lastly, the fourth group, with 41 cases, received a combination of both treatments. Study groups were evaluated double-blind. Neither the patients nor the doctor who evaluated the pain score knew which group the patients were in.

In cases where piroxicam was used, a 40 mg sublingual piroxicam was administered approximately one hour before the pregnancy termination procedure began. In the cases where local anaesthesia was applied, after the gynecological examination, a speculum was used, and the vagina and cervix were cleaned with povidone-iodine. Following this, the cervix was held with a tenaculum at the 12 o'clock position. For the second and fourth groups, at the 4 o'clock, 8 o'clock, and 12 o'clock positions, an average of 3 ml (20 mg/ml) of lidocaine hydrochloride without epinephrine was injected.

In all cases, the cervix was dilated using flexible Carmen cannulas numbered 5 and 6. Subsequently, the uterine contents were evacuated using the same flexible Carmen cannula and a 50 cc handheld vacuum aspirator. Afterwards, in all cases, the aspiration curettage procedure was completed under sterile conditions. Ten minutes after the procedure, the pain intensity experienced by the cases during the intervention was evaluated by the patient, an observer who didn't know the groups, using a one-dimensional pain assessment method called the Five-Point Pain Scale[9]. Pain intensity assessment according to the Five-Point Pain Scale is as follows: "1: No Pain, 2: Mild Pain, 3: Moderate Pain, 4: Severe Pain, 5: Unbearable Pain."

Statistical analysis was performed using SPSS 11.5 for Windows. Categorical variables were presented using

numbers and percentages, whereas numerical variables were presented using descriptive statistics (mean and standard deviation (SD)). Distribution analysis was performed using histograms and the Shapiro-Wilk test. Intergroup categorical comparisons were performed using the Chi-square test, and numerical comparisons were performed using ANOVA for normally distributed samples, and the Kruskal-Wallis test for independent groups for which the assumption was not met. Pairwise comparisons were adjusted using Bonferroni correction and were subjected to the Mann-Whitney U test. The level of statistical significance was accepted as $p<0.05$.

Results

The study included a total of 177 participants, and their average age was 31.02±6.14 years. The mean gestational week among the participants was 7.05±0.78. The average number of pregnancies for the participants was found to be 5.10±2.60.

There was no statistically significant difference among the groups concerning the number of pregnancies, childbirths, abortions, number of living children, last pregnancy interval, and age ($p>0.05$). Additionally, there was no statistically significant difference observed in the gestational weeks of the cases among the groups ($p>0.05$).

The study identified a statistically significant difference among the groups concerning the number of miscarriages ($p<0.05$). In the piroxicam group, there was one case that experienced eight miscarriages (with a mean of 0.38). The control group showed the highest mean with 0.57 and had a high standard deviation (0.71), contributing to the variation in the number of miscarriages among the groups.

There was also a statistically significant difference among the groups in terms of pain intensity ($p<0.001$).

The pain intensity showed a statistically significant difference among the groups ($p<0.001$). There was a statistically significant difference in pain intensity between the placebo group and the local anaesthetic group ($p<0.001$), the piroxicam group ($p<0.001$), and the piroxicam + local anaesthetic group ($p<0.01$). The pain intensity mean in the control group was higher than in the other three groups.

Between the local anaesthetic group and the piroxicam + local anaesthetic group, there was a statistically significant difference in pain intensity ($p<0.01$), with higher pain intensity reported in the local anaesthetic group. However, no statistically significant difference was found in pain intensity between the piroxicam group and the local anaesthetic group ($p>0.05$), as well as between the piroxicam group and the piroxicam + local anaesthetic group ($p>0.05$). The control group had a higher pain intensity mean compared to the other three groups.

The miscarriage, abortion, number of living children, childbirth, and pregnancy counts, the last pregnancy interval, age, and pain intensity averages of the cases are shown in Table 1.

The comparison of participants' pain intensity according to groups is shown in Table 2.

In the control group, 14 cases (35%) experienced mild abdominal pain, 8 cases (20%) reported nausea, and 7 cases (17.5%) had minimal vaginal bleeding, which did not exceed 50 ccs. In the piroxicam group, 7 cases (14.5%) had mild abdominal and/or epigastric pain, and 6 cases (12.5%) experienced nausea. In the piroxicam + local anaesthetic

Table 1. Averages of Miscarriage, Abortion, Number of Living Children, Childbirth, and Pregnancy Counts, Last Pregnancy Interval, Age, and Pain Intensity of 177 Cases.

	Total n=177 Mean±SD	Control n=40 Mean±SD	Piroxicam n=48 Mean±SD	Local Anesthetic n=48 Mean±SD	Local An.+ Piroxicam n=41 Mean±SD	p
Miscarriage Count	0.33±0.83	0.57±0.71[a]	0.38±1.27	0.15±0.41[a]	0.27±0.59[a]	<0.05*
Abortion Count	0.91±1.21	0.83±1.20	1.21±1.35	0.98±1.18	0.56±1.03	>0.05*
Number of Living Children	2.64±1.51	2.73±1.45	3.0±1.94	2.23±1.15	2.63±1.30	>0.05*
Number of Childbirths	2.86±1.70	3.08±1:80	3.17±2.06	2.42±1.35	2.83±1.41	>0.05*
Number of Pregnancies	5.10±2.60	5.48±2.58	5.75±3.15	4.54±2.03	4.61±2.35	>0.05*
Last Pregnancy Interval (Years)	3.70±3.41	3.05±3.37	3.79±3.39	4.13±3.93	3.77±2.84	>0.05**
Gestational Week	7.05±0.78	6.90±0.89	7.22±0.74	7.18±0.65	6.85±0.79	>0.05**
Age (Years)	31.02±6.14	31.50±7.05	31.83±5.99	30.46±5.85	30.27±5.76	>0.05**
Pain Intensity	2.23±0.86	2.98±0.86[a,b]	1.98±0.64[a]	2.21±0.62[b]	1.80±0.87[b]	<0.001*

*Kruskal Wallis Test-Mann Whitney U groups; **One-way ANOVA; [ab]Same letters express significant difference between.

Table 2. Comparison of Participants' Pain Intensity Among Groups.

Pain Intensity	Control n (%)	Piroxicam n (%)	Local Anesthetic n (%)	Local Anesthetic+Piroxicam n (%)	TOTAL n (%)	p
No Pain(1)	3 (7.5)	10 (20.8)	3 (6.2)	18 (43.9)	34 (19.2)	<0.001*
Mild Pain(2)	6 (15.0)	29 (60.4)	34 (70.8)	15 (36.6)	84 (47.4)	
Moderate Pain(3)	20 (50.0)	9 (18.8)	9 (18.8)	6 (14.6)	44 (24.9)	
Severe Pain (4)	11 (27.5)	-	2 (4.2)	2 (4.9)	15 (8.5)	
TOTAL	40 (100)	48 (100)	48 (100)	41 (100)	177 (100)	

*Chi square test.

group, 12 cases (29.3%) had mild abdominal pain, 6 cases (14.6%) reported nausea, 2 cases (4.9%) experienced vomiting, and 13 cases (31.7%) had minimal vaginal bleeding. No side effects related to the local anaesthetic were observed in the group where only local anaesthetic was administered. No early complications were detected in any of the cases, and no additional treatment was required.

Discussion

In our study, the control group had the highest pain scores, followed by the groups where local anesthetic and piroxicam were used. The piroxicam + local anesthetic group had the lowest pain score. There was a statistically significant difference in pain intensity between the control group and all other groups, as well as between the local anesthetic group and the piroxicam + local anesthetic group. While no statistically significant difference was observed in pain intensity between the piroxicam group and the local anesthetic group, or between the piroxicam group and the piroxicam + local anesthetic group, the order of pain intensity from highest to lowest was as follows: control group (2.98±0.86) > lidocaine alone (2.21±0.62) > piroxicam (1.98±0.64) > piroxicam + lidocaine group (1.80±0.87).

Fear, stress, and anxiety are complaints that can be observed in patients before legal abortion and can influence the perception of pain intensity. One of the objectives of premedication is to reduce these complaints[10].

In the study conducted by Ronca et al.[11], it was found that the plasma concentration of sublingual fast-dissolving piroxicam was significantly higher and approximately 2 times greater than other soluble tablets within 5-10 minutes after administration. It is mentioned that this medication significantly reduces pain within 15 minutes after administration. In the study conducted by Ragni et al.[12], it was determined that piroxicam is effective in relieving primary dysmenorrhea and associated symptoms. It is also noted that patients tolerate it well both locally and systemically.

In their study with 57 cases, Escamilla et al.[13] concluded that intramuscular piroxicam is an effective and reliable medication for postoperative pain control. Except for one case that described epigastric burning as a side effect, all other participants evaluated the tolerability of piroxicam as excellent or good.

In a meta-analysis by Moore et al.[14] comparing the effects of single doses of 20 mg and 40 mg oral piroxicam versus placebo on postoperative pain, they evaluated three studies and found no additional studies in the updated search. They noted that piroxicam, when used as a single oral dose for the treatment of moderate to severe postoperative pain, had similar efficacy to other NSAIDs and intramuscular morphine 10 mg.

Based on our literature review, no information was found regarding the efficacy of piroxicam in legal abortion. Our study stands as the only one conducted on this subject.

Avraham et al.'s [15] study revealed a statistically significant positive impact of ibuprofen on pain relief requirements during medical abortion with the mifepristone and misoprostol regimen compared to the placebo medication. In the study conducted by Mustafa-Mikhail et al. [16], it was found that patients who received lornoxicam after dilation and curettage (D&C) reported less pain compared to those who received intravenous paracetamol, but the clinical difference was not statistically significant. Therefore, it was suggested to administer paracetamol intravenously for post-D&C pain management. In the study conducted by Allen et al. [17], it was shown that preoperative nonsteroidal anti-inflammatory drugs (NSAIDs) reduced postoperative pain in surgical abortion procedures. The study also demonstrated that the use of 20 ml of 1% lidocaine with a tampon reduced pain during the procedure, but waiting for 3 minutes for the anesthesia to take effect during cervical anesthesia did not improve pain scores.

The study by Vural et al. [18] involved 120 cases with pregnancies of 6-9 weeks, comparing the analgesic effects of local anesthesia (lidocaine hydrochloride) and the nonsteroidal anti-inflammatory drug ketorolac tromethamine during aspiration curettage for pregnancy termination. It was found that ketorolac alone was less successful in providing analgesia compared to local anesthesia, but the combination of both did not show a significant difference in analgesia compared to local anesthesia alone. The study concluded that under the correct technique, pregnancy termination under local anesthesia caused mild pain that was acceptable to the majority of patients (80%) and, therefore, was efficient. The necessity of using analgesics and/or anesthetics in the termination of pregnancies between 6-9 weeks using the aspiration curettage method is evident.

Strausz and colleagues conducted a study involving 500 cases to evaluate the use of paracervical block and vacuum aspiration for the termination of first-trimester pregnancies. Pre-procedure sedation was provided to patients using oral Valium in doses ranging from 3 to 10 mg. The study found that complications such as perforation occurred in 0.2% of cases, vaginal laceration in 4.6%, nausea in 2.0%, hysteria in 1.2%, and bleeding requiring hospitalization in 1.8%. Based on their findings, the authors concluded that vacuum aspiration with paracervical block is an effective and preferred method for terminating first-trimester pregnancies[19]. In our study, no major complications were detected in a similar manner.

Weibe and colleagues investigated the effect of lidocaine hydrochloride and carbonized lidocaine deep and superficial injections on pain control in pregnancy terminations. Thirty minutes before the operation, 1 mg sublingual lorazepam was administered to willing patients. Although carbonized lidocaine provided better pain control, results were not clinically significant. On the other hand, deep injection resulted in better pain control compared to superficial injection, and they observed no complications such as lacerations or bleeding in hundreds of patients who underwent this method[20]. In our study, the deep injection method of lidocaine was utilized for the paracervical block as well.

Urquhart and Templeton conducted a study involving 91 cases, where patients with pregnancies of less than 64 days were divided into two groups. The first group received mifepristone and gemeprost, while the second group underwent legal abortion using the vacuum aspiration method. Notably, in the medical abortion method applied particularly to younger and nulliparous women, a greater need for analgesia was observed. Additionally, more pain and complaints of vaginal bleeding were identified among women in the first group[21].

In our study, it has been demonstrated that the combined use of oral piroxicam and local anesthetic by paracervical block is more effective in pain control during aspiration curettage compared to cases involving only local anesthetic, sublingual piroxicam, or no medications.

Limitation

The limitation of the study is that control group patients had to be recruited from another hospital. A comparison article of lidocaine and piroxicam as anesthetics and analgesics in aspiration curettage has not been found in the literature.

Conclusion

In our study, there were significant differences in pain intensity among the groups. There was a statistically significant difference in pain intensity between the control group and all other groups, as well as between the group with only local anesthetic and the group with combined piroxicam and local anesthetic. Sublingually administered piroxicam provided better pain control compared to paracervical block with lidocaine hydrochloride, but there was no significant difference between the two methods in terms of clinical and statistical outcomes. However, in cases where piroxicam and paracervical block were used together, better pain control was achieved compared to cases where only paracervical block was performed. Lidocaine hydrochloride and piroxicam were well tolerated by the participants. In conclusion, for uterine aspiration in 5-9 weeks of pregnancy, the combination of paracervical block with lidocaine hydrochloride and piroxicam was considered an effective, safe, and well-controlled method for pain relief.

Ethics Committee Approval: The study received approval on August 29, 2023, and was assigned the reference number E-62977267-903.99-223958174.

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