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Ketorolac for Pain Control With Intrauterine Device Placement: A Randomized Controlled Trial

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Abstract

Objective—To evaluate intramuscular ketorolac compared to placebo saline injection for pain control with intrauterine device (IUD) placement.

Methods—We conducted a randomized, double-blind, placebo controlled trial between July 2012 and March 2014. Patients received ketorolac 30mg or placebo saline intramuscular injection 30 minutes prior to IUD placement. The primary outcome was pain with IUD placement on a 10cm visual analog scale (VAS). Sample size was calculated to provide 80% power to show a 2.0cm difference ($\alpha=0.05$) in the primary outcome. Secondary outcomes included pain with study drug injection, speculum insertion, tenaculum placement, uterine sounding, and at 5 and 15 minutes after IUD placement.

Results—A total of 67 women participated in the study, 33 in the ketorolac arm and 34 in the placebo arm. There were no differences in baseline demographics including age, BMI, and race. There were no differences in median pain scores for IUD placement in the placebo versus ketorolac groups (5.2cm vs 3.6cm, $p=0.99$). There was a decrease in median pain scores at 5 minutes (2.2cm vs 0.3cm, $p<0.001$) and 15 minutes (1.6cm vs 0.1cm, $p<0.001$) after IUD placement but no difference for all other time points. Nulliparous participants ($n=16$, 8 per arm) had a decrease in pain scores with IUD placement (8.1cm vs 5.4cm, $p=0.02$). In this study, 22% of participants in the placebo group and 18% in the ketorolac group reported injection pain was as painful as IUD placement.

Conclusions—Ketorolac does not reduce pain with IUD placement but does reduce pain at 5 and 15 minutes after placement.

Introduction

Intrauterine devices (IUDs) are safe and highly effective birth control.¹ Despite this, they were utilized by only 7.2% of reproductive aged women in the United States from

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2011-2013.² One barrier to using IUDs may be the perception of pain involved with placement.³⁻⁶

The American College of Obstetricians and Gynecologists recommends taking over-the-counter pain medication before IUD placement, however no specific medication is recommended.⁷ Methods that have been studied include non-steroidal anti-inflammatory drugs (NSAIDs), misoprostol, and local anesthetics. Despite the use of these medications in practice, few studies have shown benefit.⁸⁻¹² NSAIDs, however, may help reduce pain. Oral naproxen sodium taken 1 hour prior to IUD placement may decrease pain with placement.^{13,14} However, waiting 1 hour may not be possible in a busy clinic.

Intramuscular ketorolac has an onset of analgesia at approximately 30 minutes. It is a potent acetic acid NSAID. It is indicated for short-term moderate acute pain and is often used in the post-operative setting.¹⁵ The maximal effect is at 1-2 hours with a 4-6 hour duration of analgesia.¹⁶ In studies of suction curettage, use of ketorolac demonstrated a decrease in acetaminophen requirement post-operatively but no difference in pain control between ketorolac and ibuprofen.^{17,18}

Ketorolac may be useful in the clinic setting given its quicker onset of action compared to oral medications. This study was designed to assess whether administering intramuscular ketorolac 30 minutes prior to IUD placement would result in a reduction in pain scores compared to placebo injection.

Materials and Methods

This was a randomized, double-blind, placebo controlled trial. It was approved by the University of California San Diego Institutional Review Board. Recruitment took place at the University of California San Diego Women's Health Clinics, which is part of an urban academic institution. Clinicians included Obstetrics and Gynecology first, second, third, and fourth year residents as well as attending physicians.

Women who were eligible for the study included those ages 18-50, nulliparous or multiparous, English or Spanish speaking, and those presenting for either levonorgestrel or TCU 380A IUD placement. Women were excluded if they were pregnant, had any diagnosed chronic pain issues (including fibromyalgia, endometriosis, dysmenorrhea, irritable bowel syndrome, interstitial cystitis), had taken any pain medications within 6 hours of enrollment, had misoprostol within 24 hours of enrollment, had a history of prior IUD insertion, had a known allergy or contraindication to NSAIDs, or had any known contraindications to IUD placement.

Subjects underwent informed consent by trained registered nurses or by the first author. They signed a written consent approved by the University of California San Diego Institutional Review Board, which was available in English and Spanish. A recruitment log tracked patients who were approached and declined participation or were ineligible for participation.

Patients were randomized to receive either ketorolac 30 mg (1 mL volume) or placebo injection of normal saline (1 mL volume). Injection was into the upper outer quadrant of the gluteus muscle. A timer was used to monitor when 30 minutes was completed. The clinicians started the IUD placement procedure immediately after the timer alarmed. Time between study medication administration and IUD placement was not recorded.

Randomization was stratified by parity, nulliparous versus multiparous, with a block size of four, and a 1:1 allocation ratio. The randomization allocation sequence was computer generated with a random number generator by a statistician not otherwise involved in the study. Group assignment was concealed in sealed, numbered, and opaque envelopes opened only by the clinic nurse administering the study drug. Clinicians and participants were blinded to group allocation. When available, a blinded clinic staff member administered study forms during the course of the procedure. However, given research and clinic staff limitations, the majority of participants were administered study forms by the un-blinded nurse.

The primary outcome of interest was pain level measured on a visual analog scale (VAS) from 0 cm (no pain) to 10 cm (worst pain possible) for IUD placement. Secondary outcomes were pain levels measured at 6 other time points: 1) study drug administration, 2) speculum placement, 3) tenaculum placement, 4) uterine sounding, 5) 5 minutes after IUD placement and 6) 15 minutes after IUD placement. We also measured anticipated pain prior to study drug administration. Participants marked their pain scores immediately after each procedure step. Of note, participants did not receive any anesthetic agent for tenaculum placement.

A post-procedural questionnaire was completed by each provider and participant. The provider questionnaire collected information including level of training, the type of IUD placed, the purpose of the IUD placement, uterine position, and any complications. Each patient received a questionnaire at the 15 minute post-procedure time point which assessed for possible adverse effects from the study drug (including nausea, vomiting, heartburn, dizziness or drowsiness, and injection site pain), pain from the injection compared to pain with the procedure, overall satisfaction with the procedure, and desire for any additional pain medication. Study participants were offered acetaminophen at the 15 minute post procedure time point (after all VAS pain scores were assessed) as additional pain medication and as another marker of pain control. We chose acetaminophen because it was readily available in our clinic, would not impair the subject's ability to drive, and was safe to take with ketorolac. At the conclusion of the study, participants were compensated with a gift card. Charts were reviewed at a later date to determine if participants called the clinic within 24 hours of enrollment to request stronger pain medications.

The power calculation was based on previous studies assessing pain control with IUD placement using a 10cm (100mm) VAS scale.^{12, 19} A clinically significant difference in VAS pain score has been defined as 1.3 cm to 2.0 cm.^{20, 21} Using a standard deviation of 2.7cm and a clinically significant pain difference of 2.0cm, in order to obtain 80% power with a 5% alpha error rate, 57 participants were needed.²⁰ To allow room for missing data and participants who may discontinue, we planned to recruit approximately 66 participants, with 33 per arm. All data entry was performed twice to ensure accuracy.

The data was analyzed based on an intention to treat analysis. For our statistical analysis, we tested the pain scores (continuous variables) for normality and they were found to have a non-normal distribution. Therefore, pain scores were compared using the Wilcoxon rank sum test. We also performed a subgroup analysis by parity, which was decided upon *a priori*. For demographics and questionnaires the chi-squared test was used to compare categorical variables and the t-test or Wilcoxon rank sum test was used to compare continuous variables. Statistical analyses were performed using PASW® Statistics Version 18 and SAS® 9.4 software.

Results

Participants were enrolled from July 2012 until March 2014. A total of 110 patients were approached for eligibility. Thirty-four of the patients approached to participate were excluded because they did not meet inclusion criteria (the majority had a prior IUD or had taken pain medications prior to the visit). Nine patients declined to participate for reasons including not wanting to wait and fear of injections. A total of 67 participants were randomized, with 33 participants allocated to the ketorolac arm and 34 participants allocated to the placebo arm (Figure 1). All patients randomized received the assigned study drug, underwent successful IUD placement, and completed the study.

There were no differences in baseline demographics including age, body mass index, gravidity, parity, race, education, current breastfeeding, and prior history of cone biopsy or loop electrosurgical excisional procedure of the cervix. The majority of patients in both groups were either Caucasian or Hispanic. Almost all patients had attended high school (Table 1).

Median pain scores for all participants were compared between placebo and ketorolac groups for the primary and secondary outcomes of pain scores. There was no difference in anticipated pain between the two groups (4.4cm vs 3.5cm, $p=0.31$) or for pain with study drug injection (1.0cm vs 0.6cm, $p=0.33$). Uterine sounding (5.0cm vs 4.3cm, $p=0.64$) and IUD placement (5.2 cm vs 3.6 cm, $p=0.99$) had the highest pain scores without a difference between the two groups. There was also no difference for speculum or tenaculum placement. There was a decrease in pain scores at 5 minutes after IUD placement (2.2cm vs 0.3cm, $p<0.001$) as well as at 15 minutes after IUD placement (1.6cm vs. 0.1cm, $p<0.001$). Results for all patients are outlined in Table 2 and Figure 2.

In our subgroup analysis, nulliparous patients ($n = 16$, with 8 in each arm), had a decrease in median pain scores with uterine sounding (8.4cm vs 6.0cm, $p = 0.04$) and IUD placement (8.1cm vs 5.4cm, $p = 0.02$). There was no difference in pain scores at 5 minutes after placement (3.7cm vs. 2.7cm, $p = 0.32$) but there was a decrease at 15 minutes after placement (4.8cm vs. 1.8cm, $p = 0.02$). For multiparous patients, there was a decrease in pain scores at 5 minutes (1.3 cm vs 0.1 cm, $p = <0.001$) and 15 minutes (1.3cm vs 0.0cm, $p = <0.001$). Of note, median pains scores for IUD placement were higher in the nulliparous subgroup compared to the multiparous subgroup (8.1cm vs 3.7cm in the placebo arm and 5.4cm vs 2.5cm in the ketorolac arm) (Table 2).

The postprocedure participant questionnaire revealed few minor adverse effects from study drug administration and no difference between the two groups. The majority of patients felt that the pain from the injection was “not as bad” as pain from IUD placement (71% vs. 81%). However, 22% in the placebo group and 18% in the ketorolac group reported the pain was just as bad as the IUD placement procedure. The majority of patients were very satisfied or satisfied with their procedure (90% vs. 93%) and would recommend IUD placement to a friend (85% vs. 91%). There were no statistically significant differences in these findings, though the study was not powered to evaluate these outcomes (Table 3).

The post-procedure provider questionnaire revealed that at 15 minutes after IUD placement, significantly more participants in the placebo group received acetaminophen compared to the ketorolac group (52% vs. 21%, $p = 0.02$). No major adverse events from IUD placement were reported by clinicians. There were no differences for type of IUD placed (levonorgestrel releasing or TCu 380A), purpose of IUD placement (contraception or menorrhagia), uterine position (anteverted, mid-positioned, or retroverted), need for cervical dilation (2 patients per group), and level of provider performing the procedure (Table 4). On review of electronic medical records, no participants called to request stronger pain medications within 24 hours of enrollment. Of note, the study was not powered to detect a difference for any of these categories.

Discussion

In our overall analysis we did not find a decrease in pain scores for IUD placement. However, this study was not powered to detect a difference less than 2.0cm. The study does support intramuscular ketorolac for decreasing pain after IUD placement. This was demonstrated with lower pain scores and less acetaminophen requirement at 15 minutes after placement.

Nulliparous participants showed a decrease in pain for uterine sounding and IUD placement. However, these results must be interpreted with caution. The study was not powered for subgroup analysis by parity or other subgroups such as IUD type. A p value adjustment may lead to a non-significant result for uterine sounding and a borderline significant result for IUD placement. In addition, given the small sample size of 16 subjects, the results may be due to chance and may not be generalizable. A trial powered for subgroup analysis may clarify the effects of ketorolac.

While ketorolac has a maximal effect at 1-2 hours, we chose to study it at the time of onset, 30 minutes. This was a more realistic wait time for our busy clinic. This may have contributed to pain reduction noted only after the IUD procedure was completed. We did not follow participants past 15 minutes to minimize clinic flow interruptions. While this is a study limitation, compared to other NSAID trials, we did demonstrate a post-procedural benefit.

Many of the oral NSAID trials are limited by short time to IUD placement and lack of follow up pain scores. Ibuprofen was administered up to 45 minutes prior to placement in 3 of 4 trials, so there may not have been sufficient time for analgesic effect. Pain after

placement was not evaluated in these trials. Jensen *et al.* did not observe a difference during or after placement with ibuprofen 1-4 hours prior to placement. However, post-procedural pain was evaluated 4-6 hours after placement, when the ibuprofen may not have been therapeutic.^{19, 22-24} Naproxen sodium 550mg reduces pain with Multiload Cu 375 IUD placement though follow up pain scores were not evaluated. Of note, this trial was published after the start of the present trial.¹³ A trial of naproxen sodium 300mg with the Dalkon Shield IUD did not reduce pain with placement, but did reduce pain medication requirement post-procedure.¹⁴ Naproxen sodium may have demonstrated efficacy because sufficient time was given for onset of analgesia. Trials directly comparing efficacy of naproxen, ibuprofen, and ketorolac in a procedural setting are not available, so it is unclear if there is a physiologic basis for the differences observed.

The strength of this study is that it is a double-blind, randomized, placebo controlled trial. Ketorolac is a relatively inexpensive medication, costing about \$1 per dose. It can be stocked in clinics. It has a wait time of 30 minutes compared to 1 hour for oral NSAIDs with analgesia lasting 4-6 hours. Injection pain scores were objectively low compared to IUD placement pain. However, 20% of patients reported their injection site pain after 15 minutes was just as bad as their IUD placement.

There are limitations to this study. Staff administering study forms were un-blinded to treatment allocation because of limited research personnel. This may have resulted in a bias toward a beneficial effect. However, participants marked their own pain score, with study staff only holding up the VAS forms. This helped to limit potential bias. Another limitation is that ketorolac may not be available in all clinics. When it is given, a healthcare provider must be available to administer the injection.

Patient satisfaction was high regardless of treatment allocation, likely because IUD placement is a short procedure and all participants had successful placement. Pain scores were higher at 15 minutes compared to 5 minutes for the nulliparous control group, the reason for which is unclear but may be due to increased endometrial irritation from the IUD absent an NSAID effect. We did not perform ultrasound assessment to confirm IUD placement, though it may have been helpful to identify a small number of IUD embedment cases.

The demonstrated efficacy of ketorolac in this study is encouraging. However, it is limited by the need for a potentially painful intramuscular injection and an in clinic 30 minute wait time. An oral medication, such as naproxen sodium, taken prior to clinic arrival may be more practical. Additional studies on the efficacy of naproxen sodium during and after IUD placement would be helpful. Ultimately, we hope decreasing pain associated with IUD placement can help increase utilization of this highly effective contraceptive method.

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Figure 1. Study flowchart. Out of 110 women who were approached for eligibility, a total of 67 were included in the analysis. All allocated participants received their assigned study drug. IUD, intrauterine device.

Figure 2. Visual analog scale pain scores for all time points. Median pain scores with interquartile ranges (25%, 75%) comparing the placebo and ketorolac groups for (A) the entire sample and (B) the nulliparous subgroup. * $P < 0.05$. IUD, intrauterine device.

Table 1
Demographics of study participants

	Placebo Saline Injection (n=34)	Ketorolac Injection (n=33)
Age , mean years (SD)	27.3 (5.4)	26.6 (5.1)
Body mass index , mean (SD)	27.6 (5.7)	27.3 (5.8)
Race/Ethnicity		
- Caucasian	13	12
- Hispanic	4	2
- African American	14	12
- Asian/Pacific Islander	1	4
- Other	2	3
Education		
- Less than high school	0	1
- High school graduate	7	4
- Some college	12	11
- College degree	7	6
- Graduate degree	7	11
Gravidity , median[IQR]	1 [1.2]	1 [1.2]
Parity , median [IQR]	1 [1,1]	1 [1.2]
Currently breastfeeding	15	15
History of LEEP	0	3

Table 2
Median pain scores for all time points

	Placebo median [25%,75%] [£]	Ketorolac median [25%,75%] [£]	Difference in scores	P-value [*]
All participants	n = 34	n = 33		
anticipated pain	4.4 [1.4,6.5]	3.5 [1.0,6.8]	0.9	0.31
pain with injection	1.0 [0.4, 2.8]	0.6 [0.2,1.3]	0.4	0.33
speculum insertion	2.6 [0.6,3.7]	1.5 [0.4,3.8]	1.1	0.72
tenaculum placement	3.9 [2.6,5.7]	2.5 [1.1,6.4]	1.4	0.36
uterine sounding	5.0 [2.5,7.5]	4.3 [1.7,7.2]	0.7	0.64
IUD placement	5.2 [1.2,7.4]	3.6 [1.5,6.3]	1.6	0.99
5 min after insertion	2.2 [0.8,3.9]	0.3 [0.1,3]	1.9	<0.001
15 min after insertion	1.6 [0.4,3.6]	0.1 [0.0,9]	1.5	<0.001
Nulliparous	n = 8	n = 8		
anticipated pain	2.8 [0.8,5.4]	3.6 [2.0,5.5]	0.8	0.60
pain with injection	1.8 [0.7,3.4]	1.2 [0.8,2.7]	0.6	1.00
speculum insertion	2.3 [1.0,4.5]	1.5 [0.3,3.1]	0.8	0.34
tenaculum placement	6.3 [3.7,7.3]	4.3 [2.2,7.1]	2.0	0.32
uterine sounding	8.4 [6.6,9.2]	6.0 [3.9,6.7]	2.4	0.04
IUD placement	8.1 [7.4,9.0]	5.4 [5.0,7.4]	2.7	0.02
5 min after insertion	3.7 [2.3,4.8]	2.7 [1.5,3.3]	1.0	0.32
15 min after insertion	4.8 [3.0,6.9]	1.8 [0.2,3.2]	3.0	0.02
Multiparous	n = 26	n = 25		
anticipated pain	4.7 [1.9,6.8]	3.4 [0.9,6.8]	1.3	0.31
pain with injection	0.8 [0.3,1.9]	0.6 [0.2,1.1]	0.2	0.33
speculum insertion	2.8 [0.6,3.6]	1.5 [0.5,4.0]	1.3	0.72
tenaculum placement	3.7 [1.4,5.2]	2.4 [0.7,5.5]	1.3	0.36
uterine sounding	3.7 [1.8,6.6]	2.9 [1.0,7.3]	0.8	0.64
IUD placement	3.7 [0.6,6.1]	2.5 [1.0,5.5]	1.2	0.99
5 min after insertion	1.3 [0.4,3.2]	0.1 [0.0,5]	1.2	<0.001
15 min after insertion	1.3 [0.4,2.6]	0.0 [0.0,2]	1.3	<0.001

Pain scores reported in centimeters on a 0 to 10cm visual analog scale.

* p value obtained from a Wilcoxon rank sum test.

[£] Represents the interquartile range (25%, 75%).

Table 3
Results of the participant survey completed at 15 minutes after IUD placement

	Placebo Saline Injection, n=34 (%)	Ketorolac Injection, n=33 (%)	p-value *
Reported Side Effects			
- Nausea	2	0	0.49
- Vomiting	0	0	--
- Dyspepsia (heartburn)	0	0	--
- Headache	3	0	0.24
- Dizziness	3	2	1.00
- Drowsiness	1	1	1.00
- Injection site itchiness, swelling, or pain	3	5	0.71
Current injection site pain			0.50
-None	1 (3)	0 (0)	
- Not as bad as the IUD placement procedure	23 (72)	27 (82)	
- Just as bad as the IUD placement procedure	7 (22)	6 (18)	
- Worse than the IUD placement procedure	1 (3)	0 (0)	
Overall satisfaction with IUD insertion experience			0.76
- Very satisfied	16 (48)	18 (55)	
- Satisfied	14 (42)	13 (39)	
- Neutral	2 (6)	2 (6)	
- Dissatisfied	0 (0)	0 (0)	
- Very dissatisfied	1 (3)	0 (0)	
Recommend an IUD to a friend			0.35
- Yes	28 (85)	30 (91)	
- No	0 (0)	0 (0)	
- Not sure	5 (15)	3 (9)	
Current pain warranting additional pain medications			0.02
- Yes	16 (48)	6 (18)	
- No	18 (52)	27 (82)	

Data are n (%) unless otherwise specified.

* p values are derived from the chi-squared test.

Table 4

Results of the provider survey completed after completion of IUD placement.

	Placebo Saline Injection, n = 34 (%)	ketorolac Injection, n=33 (%)	p-value*
Level of training			0.20
- PGY-1	2 (15)	5 (15)	
- PGY-2	2 (15)	13 (39)	
- PGY-3	3 (23)	6 (18)	
- PGY-4	5 (38)	6 (18)	
- Attending	1 (8)	3 (9)	
IUD type			0.09
- Levonorgestrel-releasing	22 (65)	28 (85)	
- TCu 380A	12 (35)	5 (15)	
Purpose of IUD			1.00
- Contraception	33 (97)	32 (97)	
- Abnormal uterine bleeding	1 (3)	1 (3)	
Position of uterus			0.92
- Anteverted	19 (56)	20 (61)	
- Retroverted	6 (18)	5 (15)	
- Mid-positioned	9 (26)	8 (24)	
Need for cervical dilation			1.00
- No	32 (94)	31 (94)	
- Yes	2 (6)	2 (6)	
Completed IUD insertion			N/A
- No	0 (0)	0 (0)	
- Yes	34 (100)	33 (100)	
Significant bleeding (> 5 minutes to control)			0.24
- No	34 (100)	31 (94)	
- Yes	0 (0)	2 (6)	
Major complications			1.00
- No	33 (100)	33 (100)	
- Yes	0 (0)	0 (0)	
Acetaminophen prior leaving the office			0.02
- No	16 (48)	26 (79)	
- Yes	17 (52)	7 (21)	

Data are n (%) unless otherwise specified. Percent totals may not add up to 100 because of rounding.

* p values were derived from the chi-squared test.