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Contraception 77 (2008) 56–59

Contraception

Original research article

A randomized trial of tramadol versus ibuprofen as an adjunct to pain control during vacuum aspiration abortion☆

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Received 27 April 2007; revised 5 September 2007; accepted 5 September 2007

Abstract

Background: The study was conducted to determine whether tramadol is more effective than ibuprofen for reducing pain during uterine aspiration for abortion.
Study Design: Women presenting to a community-based abortion clinic were invited to participate in this double-blind, randomized trial. Following informed consent, subjects were randomly assigned to receive either 50 mg tramadol or 800 mg ibuprofen orally in addition to the standard clinic analgesic protocol. The primary outcome was pain as verbally rated on a scale from 0 to 10. Measurements were obtained immediately after and 30 min postprocedure.
Results: One hundred fifty-eight women were enrolled, 80 women were randomized to ibuprofen and 78 women, to tramadol. Immediately after the procedure, the mean pain scores in both treatment groups were 4.9 (95% CI=4.3–5.5). Thirty min postoperatively the mean pain score in the ibuprofen group was 2.8 compared to 3.6 in the tramadol group (p=.04).
Conclusion: There was no difference in immediate postprocedure pain between women receiving tramadol or ibuprofen. Ibuprofen is somewhat more effective than tramadol at reducing pain 30 min following surgical abortion.

Keywords: Surgical abortion; Pain control; Tramadol; Ibuprofen

1. Introduction

Elective abortion is one of the most common surgical procedures performed in the United States with 1.31 million performed in 2000 [1]. Eighty-eight percent of these are in the first trimester with various analgesic protocols [2]. A survey of 202 clinics revealed that 58% of first-trimester abortions were accomplished with the use of local cervical block with or without oral premedication, and of the clinics offering oral premedication, 76% offer nonsteroidal anti-inflammatory drugs, 41% offer an anxiolytic, and 33% offer acetaminophen with (9%) or without (24%) codeine [3]. To date, an ideal regimen for pain control during the procedure is not established.

Tramadol (Ultram, Ortho-McNeil, Raritan, NJ, USA) is a synthetic, centrally acting analgesic agent used throughout Europe since the late 1970s and has been marketed in the United States since 1998. It has two distinct, synergistic mechanisms of action, it acts as a weak opioid agonist and as an inhibitor of norepinephrine and serotonin reuptake [4]. For perioperative pain, tramadol has been shown to be well tolerated and more effective than nonsteroidal anti-inflammatory drugs, acetaminophen or placebo in randomized controlled trials [5,6]. Unlike opioids, tramadol has no clinically relevant effects on cardiovascular or respiratory parameters at recommended doses [7]. Tramadol has not been evaluated as an adjunct to pain relief during abortion. Given the efficacy of tramadol as an analgesic during other surgical procedures, we hypothesize that patients treated with tramadol prior to surgical abortion would have a lower mean pain score than those treated with ibuprofen.

☆ There was no external funding for this research.
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doi:10.1016/j.contraception.2007.09.008

2. Materials and methods

A randomized, double-blind trial was conducted at a free-standing clinic in Salt Lake City, UT, USA, between February 2004 and June 2005. Approval for the study was obtained from the Institutional Review Board at the University of Utah. Written informed consent was obtained from all participants. All study-related procedures and written material were available in English and Spanish. A computer generated random numbers table assigned subjects to the two groups. All Consolidated Standards of Reporting Trials guidelines were followed except allocation concealment. After enrollment in the study, subjects were managed according to the standard protocol for the clinic. This protocol included counseling, history, physical examination, hematocrit, Rhesus factor assessment and ultrasound for gestational duration. Demographic and reproductive information obtained included race or ethnicity, age, parity and history of prior abortion.

Women were included if they were 18 years or older, were less than 20 weeks of gestation and elected to undergo surgical termination. Subjects were excluded from participation if they had a contraindication to tramadol or ibuprofen. Contraindications to tramadol include history of epilepsy, use of selective serotonin reuptake inhibitors, tricyclic compounds, opioids, monoamine oxidase inhibitors, neuroleptics or other drugs that reduce the seizure threshold. Subjects with a reported history of addiction to opioids were also excluded from study enrollment.

The outcome measure for this study was intensity of immediate postoperative pain and pain 30 min following the procedure as measured on a validated 11-point verbal pain scale [8], previously used in several abortion studies [9–11]. Patients were asked, "On a scale of 0 to 10, where 0 is no pain and 10 is your worst pain ever, how would you rate your pain?" The sample size was calculated based on anticipated mean pain score. A prior study found that a difference in pain score of 1.3 was statistically significant [12]. We estimated that, with 71 patients in each treatment arm, there would be 80% power (β=.20) at a 5% significance level (two-sided alpha=.05) to detect a difference of 1.3 in mean pain score.

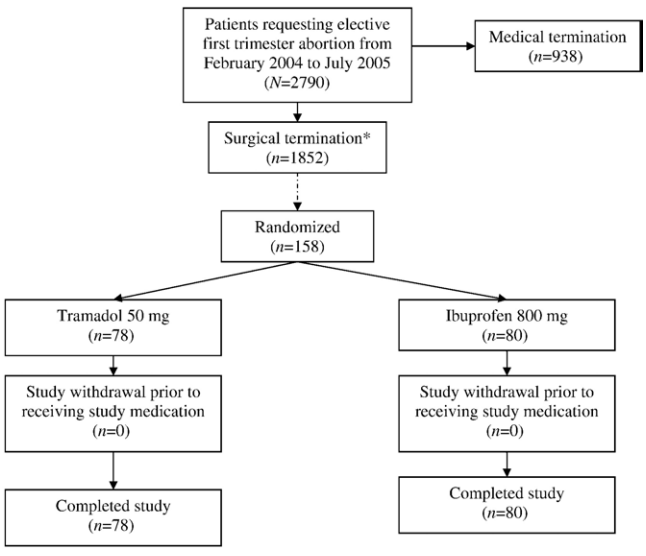

Fig. 1. Participant flow. *Not all potentially eligible subjects were approached regarding participation in the study, and the exact number of eligible patients who were offered participation in the study but declined is unknown.

Table 1
Demographic and clinical characteristics of participants by treatment group

	Ibuprofen (n=80)	Tramadol (n=78)	p value
Age (years)	28±6.3	26±5.9	.16
Gestational age (weeks)[a]	8.8±2.7	8.8±2.7	.98
Nulliparous parity	19 (24)	33 (42)	.01
1	17 (28)	19 (42)	.49
2	23 (38)	14 (31)	
3	10 (16)	6 (13)	
>4	11 (18)	6 (13)	
Prior induced abortion	28 (35)	31 (40)	.54
Race/ethnicity			
White	45 (56)	48 (62)	.50
Latino	28 (35)	22 (28)	
Other	7 (9)	8 (10)	

Data are presented as mean±S.D. with p value from independent t test or n (%) with p value from χ^2. For all variables, missing data were ≤.05%.
[a] Gestational age determined by ultrasound.

Subjects received an oral dose of either 50 mg of tramadol or 800 mg of ibuprofen 1 h before the procedure. The pills were not identical in appearance, but the individual distributing the medication was not involved in the patient's care thereafter. All subjects received a lower uterine field block consisting of 16 mL of 1% plain-buffered lidocaine and 4 mL of 1% lidocaine with epinephrine with 10 mL injected deep in the cervix at the 4- and 8-o'clock positions, and all were offered inhaled nitrous oxide during the surgical procedure. Subjects were asked to characterize their pain using the 11-point verbal pain scale immediately after the procedure was completed but not during the abortion. The intensity of pain was analyzed again 30 min later. The surgeon and the research assistant collecting information regarding pain were blinded to the treatment received by the study subject. Requests for additional analgesic medication during the postoperative period were recorded, as well as any side effects such as nausea, dizziness, headache, somnolence or seizures. Operative time was recorded beginning with insertion of the speculum and ending with removal of the speculum.

Pain scores were evaluated as continuous variables. To further characterize pain, the scores were also evaluated as ordinal and dichotomous variables. For ordinal evaluation, pain scores were designated as low if the pain score was 0–<4, moderate if 4–<7, and high if ≥7. For dichotomous variables evaluation, scores were categorized as severe (≥7) or nonsevere (<7). Comparisons of ordinal variables were made with a chi-square test for trend. Student's t test was used to compare mean pain scores between treatment groups. We used linear regression modeling to control for nulliparity and operating physician. For all statistical tests, a p value of