Medical abortion causes pain in almost all patients, which is often intense. Evidence is needed about how best to control this serious problem.

Several past research studies have evaluated various drug treatments. However, these studies had flaws: for example, they used medical abortion regimens that were outdated; the outcomes were poorly measured; or they tested regimens that might have been expected to be fairly weak. To address these issues, we designed a new study to be conducted in women undergoing first trimester abortion with mifepristone and misoprostol. Our study compared two regimens of ibuprofen: a prophylactic (or preventive) regimen, in which women started the medication before the pain began and kept taking it for two days regardless of pain, to a therapeutic regimen, in which women took the medication when they actually had pain.

METHODS

Our trial included a total of 250 women at one clinic in New York, NY, and two in Chicago, IL, between October 2011 and December 2012. Pregnant women with a gestational age of 63 days or less who intended to begin their medical abortion on the day they joined the study and who had no specified contraindications to ibuprofen were eligible to participate.

After each volunteer provided informed consent to be in the study, site staff interviewed her to make sure she was eligible and to collect baseline data. They then randomly assigned her to either the prophylactic or therapeutic regimen group. The staff gave her a supply of tablets of ibuprofen 800 mg and told her how to take them according to her group. In the prophylactic group, subjects were instructed to take the first dose of ibuprofen one hour before the misoprostol, and then one tablet every 4-6 hours after that for 48 hours whether or not she had pain. In the therapeutic group, subjects were to take one ibuprofen every 4-6 hours as needed for pain. Each woman received a diary to fill out at home to record the severity of her pain on a scale of 0-10, her use of study ibuprofen or other pain medicines, and vaginal bleeding or spotting.

When subjects returned for their follow-up visits, the site staff collected their diaries and interviewed them about their experiences with pain during and after the abortion, and also asked about any side effects. If subjects did not return, staff collected this information by telephone.

RESULTS

We were able to collect follow-up data from 228 of the 250 enrolled subjects. These women had an average age of 25 years and a mean gestational age of 47 days. Most had some education after high school. About half expected the severity of the pain from the abortion to be at least a 7 on a scale of 0-10.

Most subjects took their ibuprofen according to the instructions for their group. Subjects in the prophylactic group ended up taking substantially more tablets than women in the therapeutic group; the averages were 9 and 5, respectively.

The analysis showed no evidence of difference in pain between the two groups. In both groups, the average worst pain was rated as 7 on a scale of 0-10, about half of women had severe or unbearable pain, and the pain lasted for about 5 days. Related outcomes, such as use of pain medicine other than ibuprofen, the acceptability of the pain to the women, and whether subjects thought the ibuprofen helped, also were similar in the two groups. The prophylactic regimen did not appear to help any subgroups of women, including younger women, women who normally...
had severe menstrual cramps, or women who expected to have severe pain from the abortion. The prophylactic regimen did not appear to cause more bleeding, side effects from the ibuprofen, or abortion failures or complications.

DISCUSSION

Our study found no evidence that the prophylactic regimen of ibuprofen offered any advantage over ibuprofen as needed in decreasing pain in first trimester medical abortion. The severity of pain experienced by women in both groups was high.

We believe that these disappointing results cannot be attributed to flaws in the way we designed or carried out our study. Over 90% of women provided data about their pain; subjects mostly complied with our instructions on how to take their ibuprofen; and the quality of data collected was high.

Our findings do not provide a strong recommendation for clinical practice. Importantly, neither regimen worked well enough. More research is needed to find a better way to help women control pain in medical abortion.