Two low-dose levonorgestrel intrauterine contraceptive systems: a randomized controlled trial

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OBJECTIVE

To evaluate the efficacy and safety of two low-dose levonorgestrel intrauterine contraceptive systems.

METHODS

Nulliparous and parous women aged 18-35 years with regular menstrual cycles (21-35 days) requesting contraception were randomized to 3 years of treatment with one of two levonorgestrel intrauterine contraceptive systems: 13.5 mg total content or 19.5 mg total content. The primary outcome was the pregnancy rate, calculated as the Pearl Index.

RESULTS

Overall, 1,432 and 1,452 women in the 13.5 mg intrauterine contraceptive system and 19.5 mg intrauterine contraceptive system groups, respectively, had a placement attempted and were included in the full analysis set to evaluate efficacy and safety. Mean (standard deviation) age was 27.1 (4.8) years; 39.2% were nulliparous. Over the 3-year study period, 0.33 pregnancies per 100 women-years (95% confidence interval [CI] 0.16-0.60) were observed with the 13.5 mg intrauterine contraceptive system compared with 0.31 per 100 women-years (95% CI 0.15-0.57) with the 19.5 mg intrauterine contraceptive system. Kaplan-Meier estimates for that period were 0.009 and 0.010, respectively. At least partial expulsions occurred in 4.56% and 3.58% and discontinuation rates resulting from a reported adverse event occurred in 21.9% and 19.1%, respectively. Ten of the 20 pregnancies were ectopic. Serious adverse events included six cases of pelvic inflammatory disease and one partial uterine perforation.

CONCLUSIONS

Both lower-dose levonorgestrel intrauterine contraceptive systems were highly effective for 3 years of use and generally well tolerated.

CLINICAL TRIAL REGISTRATION

ClinicalTrials.gov, www.clinicaltrials.gov, NCT00528112.

LEVEL OF EVIDENCE: 1

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