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Letter to the Editor

Extended use of the intrauterine device: a literature review and recommendations for clinical practice

To the Editors:

I read with interest the literature review performed by Wu and Pickle [1] to assess extended use of long-acting reversible contraceptives. I applaud their enthusiasm, but I believe that their conclusion regarding extended use of the 52 mg levonorgestrel (LNG) intrauterine system (IUS), currently marketed worldwide as Mirena®, is premature.

The four studies included by Wu and Pickle to examine use of LNG IUS beyond 5 years included two using a 60-mg LNG product and two with a 52-mg product. The LNG IUS is formulated with a rate-controlling membrane that regulates LNG release; the properties of the membrane are different for each IUS. Although the studies with 60 mcg products stated that the release rate was 20 mcg/day (which is also the initial release rate for the 52-mg product) [2,3], the diminution over time cannot be considered equal to the marketed 52-mg product. Accordingly, data from a 60-mg LNG IUS cannot be extrapolated in any way to define extended efficacy for the 52-mg product.

Additionally, the authors' summary of the two 52-mg product studies was erroneous. The two studies using a 52-mg LNG IUS were both observational trials of women enrolled in a sponsor-funded study that chose to continue the product beyond 5 years. The first study, from a single center in Sweden, included 109 multiparous women who extended use for 5.3 to 8.0 years [4]. There are no clear data on the number of women who reached specific time points beyond 5 years of use. The other study included 67 parous women with a mean age of 33 years at the time the LNG IUS had been used for 5 years who were followed through 84 months of exposure [5]. Mean serum levels of LNG at 84 months varied greatly with a range from 23 to 393 pg/mL. No pregnancies were observed in either study.

The extremely small sample in these two observational studies is not enough to support recommendation of prolonged use beyond 5 years, and only one of the studies (with 67 women) clearly presented information that could be used to understand the duration of use. Additionally, the serum levels presented in the second study cannot be used to estimate extended efficacy since LNG IUS works locally in the uterus and cervix to prevent pregnancy. Serum levels are not representative of efficacy, which has also been identified by the Food and Drug Administration as a reason that a generic IUS cannot be approved.

Although, as a medical community, we want to strongly believe that the 52-mg LNG IUS is effective beyond 5 years, we are still lacking sufficient data for such recommendations. Clinical trials are ongoing that will give us these answers and we should be patient until the results are available. As contraception is preventative care, we must be sure that what we prescribe will truly prevent the undesired outcome of pregnancy.

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