

PRIORITY UPDATES FROM THE RESEARCH LITERATURE (PURLs)

Keep on Keeping on – Mirena IUD for 8 Years

Samuel Holt McNair, MD, Carl Tunink, MD, MSAM, and Laura Morris, MD, MSPH, FAAFP

Counsel patients that their Mirena IUD retains contraceptive effectiveness for extended use up to 8 years.¹ The cumulative failure rate for years 6 through 8 was 0.68%, similar to reported rates for the first 5 years of use. (J Am Board Fam Med 2025;00:000–000.)

Keywords: 52-mg Levonorgestrel releasing intrauterine system, Contraceptive effectiveness, Excessive uterine bleeding, Long-acting reversible contraception, Pearl index

Strength of Recommendation: B

Observational cohort study.¹

Illustrative Case

A healthy 26-year-old G1P1 female presents to clinic and to discuss contraception options. She has been using a 52 mg levonorgestrel intrauterine device (52 mg LNG-IUD, Mirena®) for the past 5 years and has been tolerating it well without adverse effects. She wants to continue contraception and is curious about her options including replacement of a Mirena IUD. Do you recommend continuing use of her current 52 mg levonorgestrel intrauterine device?

Clinical Context

The most effective methods of contraception include subdermal implants and intrauterine devices (IUD), known as long-acting reversible contraception (LARC). IUDs have a low failure rate, can be accessed in an outpatient setting and are a cost-effective reversible nonsurgical option. With a

minimal difference between perfect and typical use,² the IUD avoids disadvantages of many other contraceptive methods such as oral contraceptive pills. Continuous use can avoid contraceptive method switching which requires precise counseling to avoid unintended pregnancy.^{3,4} In 2014, 23% of female contraceptive users worldwide utilized an IUD.⁵ As its primary mechanism of action the 52 mg LNG-IUD inhibits fertilization by thickening cervical mucus; the local progesterone effect thins the endometrium to impair implantation. Initially, the 52 mg LNG-IUD was approved by the FDA for 5 years of use; this was extended to 7 years in 2022.

Methods

This article was identified as a potential PURL through the standard systematic methodology.⁶ An additional literature search was conducted by searching PubMed with the terms “Mirena IUD,” “levonorgestrel IUD,” and “AUB with IUD” to find additional literature to place this research into the context of current clinical practice.

Study Summary

52 mg LNG-IUD Maintains Effective Contraception through 8 Years of Use

This United States-based phase 3 multicenter prospective cohort study enrolled women aged 18 to 35 who were using a 52 mg LNG-IUD for 4.5 to 5 years to determine the contraceptive effectiveness of extended use up to 8 years (n = 362).¹ A small subset were using the 52 mg LNG-IUD for heavy menstrual bleeding (HMB) (6 patients, 1.7%).

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Corresponding author: Carl Tunink, MD, MSAM, FAAFP, University of Missouri Health Care, 1 Hospital Drive, Columbia, MO 65201 (E-mail: tuninkc@health.missouri.edu).

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Exclusion criteria included pregnancy, unexplained uterine bleeding, abnormal cervical smear, or menopause symptoms with elevated follicle-stimulating hormone levels. Most women were 26 to 35 years of age (89%), parous (53%), and White (75%), with an average BMI of 28.

Follow up occurred every 6 months over the 3 years of continuation to discuss potential adverse events, continued need for contraception, medication list updates, and to confirm IUD location. Pregnancy testing was performed at each follow up visit and pregnancy rates ascertained at 3 weeks, 3 months, and 12 months poststudy. Patients used a daily electronic diary to track uterine bleeding.

The primary study outcome was contraceptive efficacy of the 52 mg LNG-IUD as measured by the Pearl Index (the number of pregnancies per 100-patient years). There were 2 pregnancies between enrollment and the end of the study ($n = 223$ patients completed year 8). One pregnancy of unknown location resolved spontaneously, and another ectopic pregnancy resolved after administration of methotrexate and IUD removal. The 3-year Pearl Index for extended use of 52 mg LNG-IUD was 0.28 (95% CI, 0.03-1.00). Put another way, there was 1 pregnancy for every 357 patient-years during the study period. The cumulative failure rate for years 6 through 8 was 0.68%.

Bleeding patterns remained favorable for HMB patients through the duration of the study, though there were not enough participants to determine statistical or clinical significance.

One hundred thirty-nine patients (38%) withdrew from the study, most commonly due to desire for pregnancy ($n = 44$, 12.2%), withdrawal by subject ($n = 33$, 9.1%), and adverse events ($n = 27$, 7.5%; most commonly bleeding or pain). Loss to follow-up during extended use was 7.5% ($n = 26$). Following withdrawal or the conclusion of the study there was a 12 month return to fertility rate of 77% in those who desired pregnancy.

What Is New

First Study to Evaluate Efficacy of 52 mg LNG-IUD for 8 Years Showed Continued Effective Contraception

Both 52 mg LNG-IUDs (Liletta[®] and Mirena[®]) were previously approved by the US Food and Drug Administration for contraception through 7 years of use.⁶ This study demonstrates continued effectiveness through 8 years for Mirena[®], while an

additional study published in 2022 confirms similar effectiveness through year 8 for Liletta[®].¹¹ The Pearl Index (PI) through year 8 was similar to that seen in earlier studies of the 52 mg LNG-IUD (5-year PI 0.2; 95% CI, 0.01 -1.13).^{8,9} Further, the rate of adverse events leading to discontinuation was similar to previous studies of 52 mg LNG-IUD.¹⁰

Caveats

There were too few patients in this study to assess extended use of the 52 mg LNG-IUD for both contraception and heavy menstrual bleeding. That stated, approximately half of the patients reported either amenorrhea or infrequent bleeding during the extended use period and only 11 women (3%) discontinued the IUD due to bleeding-related adverse events. Since the initial study enrolled women as young as 18 years of age, effectiveness of extended use may be different when an IUD is initiated in a younger teen. In addition, the rate of pregnancy among the 7.5% of women lost to follow-up is uncertain.

Challenges to Implementation

Clinicians have been slow to adopt recent recommendations for 7-year extended use of LNG-IUDs, and this study leads to additional practice changes in a relatively short period of time. The lifespan of the IUD is off-cycle with cervical cancer screening recommendations for many women, which may lead some to decide to replace their IUD earlier than 8 years to avoid duplicate exams or extra office visits.

To see this article online, please go to: <http://jabfm.org/content/00/00/000.full>.

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