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Prolonged Use of the Etonogestrel Implant and Levonorgestrel Intrauterine Device - Two Years Beyond FDA-Approved Duration

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Abstract

Background—The subdermal contraceptive implant, and the 52mg levonorgestrel intrauterine device (IUD) are currently FDA-approved for three and five years of use respectively. Limited available data has suggested both of these methods are effective beyond that time. Demonstration of prolonged effectiveness will improve the cost-effectiveness of the device, and potentially patient continuation and satisfaction.

Objective—To evaluate the effectiveness of the contraceptive implant and the 52-mg hormonal intrauterine device (IUD) in women using the method for two years beyond the current FDA-approved duration.

Study Design—We initiated this ongoing prospective cohort study in January 2012. We are enrolling women using the contraceptive implant or 52-mg levonorgestrel IUD for a minimum of 3 and 5 years, respectively (started IUD in 2007 or later or implant in 2009 or later). Demographic and reproductive health histories, as well as objective body mass index (BMI) were collected. Implant users were offered periodic venipuncture for analysis of serum etonogestrel levels. The primary outcome, unintended pregnancy rates, was calculated per 100 woman-years. We analyzed baseline demographic characteristics using chi-square test and Fisher Exact test, and compared serum ENG levels stratified by body mass index using the Kruskal-Wallis test.

Results—Implant users (n=291) have contributed 444.0 women-years of follow-up. There have been no documented pregnancies in implant users during the two years of post-expiration follow-up. Calculated failure rates in the fourth and fifth years for the implant are calculated as 0 (one-sided %97.5 confidence interval (CI) 0–1.48) per 100 woman years at four years and 0 (one-sided %97.5 CI 0–2.65) per 100 women years at five years. Among 496 levonorgestrel IUD users, 696.9 women-years of follow-up have been completed. Two pregnancies have been reported. The failure

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rate in the sixth year of use of the levonorgestrel IUD is calculated as 0.25(%95 CI 0.04–1.42) per 100 women year; failure rate during the seventh year is 0.43 (%95 CI 0.08–2.39) per 100 women years. Among implant users with serum etonogestrel results, the median etonogestrel level at the time of method expiration was 207.7 pg/mL (range 63.8–802.6 pg/mL), 166.1 pg/mL (range 67.9 25.0 – 470.5 pg/mL) at the end of the fourth year, and 153.0 pg/mL (range 72.1–538.8 pg/mL) at the end of the fifth year. Median ENG levels were compared by BMI at each time point and a statistical difference was noted at the end of four years of use with overweight women having the highest serum ENG (195.9 pg/ml: range 25.0–450.5) when compared to normal (178.9 pg/ml: range 87.0–463.7) and obese (137.9 pg/ml: range 66.0–470.5) women (p=0.04).

Conclusion—This study indicates that the contraceptive implant and 52-mg hormonal IUD continue to be highly effective for at least two additional years of use. Serum etonogestrel evaluation demonstrates median levels remain above the ovulation threshold of 90pg/ml for women of in all BMI classes.

Keywords

FDA-approved duration; IUD; implant; prolonged use; effectiveness

Introduction

Long acting reversible contraception (LARC) continues to gain popularity and recent estimates suggest that as many as 12% of US women actively contracepting are using an IUD or implant.[1] Improving access to these methods is an important strategy to increasing uptake. Many access barriers still exist for women both domestically and internationally. One way to improve LARC utilization is to demonstrate safety, efficacy, and cost-effectiveness for time periods beyond the current U.S. Food and Drug Administration (FDA) duration of use. Evidence exists to support the prolonged use of the etonogestrel implant and the 52 mg levonorgestrel intrauterine device (LNG IUD) for at least one year beyond FDA-approved duration.[2–5] Data from the World Health Organization (WHO) study group on the subdermal implant recently published findings in which there were no documented pregnancies in women using the ENG implant during years 4 and 5.[6] We have found scant data in the medical literature for contraceptive effectiveness beyond 6 years for the LNG-IUD.

We have previously published data from the EPIC (Effectiveness the Prolonged Use of the IUD and Implant) study in which one year of additional use was evaluated.[2] In this current report, we present an analysis of the effectiveness of the subdermal implant and LNG IUD after an additional year of follow-up (2 years beyond FDA-approved duration). We also present comparison data of serum ENG levels by body mass index (BMI) at each additional year of implant use.

Materials and Methods

The EPIC study was launched at Washington University in St. Louis in 2012. The study began as a prospective cohort study of the LNG IUD and implant. However, the study now has several components: 1) a randomized trial of continued use of the implant beyond the

FDA-approved duration compared to a new implant; 2) observational study of both the LNG IUD and implant; and 3) the “removal study” which follows women prospectively who have their implant or LNG IUD removed, but do not desire conception. This manuscript will focus on the results of the observational cohort study through 2 additional years of implant and LNG IUD use beyond the FDA-approved duration. The study protocol was approved by the Institutional Review Board at Washington University in St. Louis prior to participant recruitment.

Enrollment for the EPIC study began in January 2012 and is currently ongoing. We analyzed data from participants enrolled between January 2012 and July 2016. Women who initiated use of their implant as early as 2009 and their LNG IUD in 2007 and beyond were eligible to participate in this observational study. Women eligible for EPIC are between the ages of 18 and 45 years of age, English or Spanish-speaking, sexually active with a male partner, not interested in conception in the next 12 months, and willing to continue to use of their subdermal implant or LNG IUD for a minimum of an additional one year. Desire to avoid pregnancy for at least 12 months was included to ensure the study was meeting its objective of determining effectiveness of the methods beyond their current FDA-approved duration. Participants had to present within 3 months of the current FDA-approved duration of use (e.g. for implant: 33–39 months of use; 57–63 months of use for LNG IUD). Among the cohort, 87.4% of participants (N= 688) were enrolled as former participants of The Contraceptive CHOICE Project, a prospective cohort study of 9,256 participants using a range of contraceptive methods. Of the entire EPIC cohort, 12.6% were recruited from outside clinics. Date of method expiration is validated for 100% of the CHOICE participants and a subset of those enrolled from outside facilities using medical chart review for greater than 90% of the cohort.

At study enrollment participants provide written informed consent and complete a staff-administered reproductive health survey that includes questions regarding demographic characteristics including socioeconomic status. Participants were considered low socioeconmic if they reported any of the following; receiving food stamps, WIC, Welfare, or unemployment, or if they reported having trouble paying for transportation, housing, medical care or food. We also collected data regarding intercourse frequency, additional contraceptive method use, menstrual cycle regularity, partner characteristics, and presence of comorbidities that may affect fertility. Participants also undergo objective measurement of height and weight. BMI was calculated as weight in kilograms divided by height in meters squared. Participants were classified into one of three BMI categories as defined by the World Health Organization, combining the underweight and normal weight categories.[7] Normal weight women were defined as those with a BMI less than 25.0, overweight as 25.0–29.9, and obese as greater than or equal to 30.0.

Telephone follow-up surveys are completed every 6 months for 36 months or until the participant requests device removal. Once enrollment is complete, all follow-up can be completed by telephone, unless a participant requests a clinic visit. All participants are encouraged to call the study staff and arrange a clinic visit with any concern for pregnancy. Follow-up surveys assess for current method use, use of additional contraceptive methods, frequency of intercourse, and any pregnancies experienced. If a participant reports a

pregnancy that was not evaluated with the study team, medical record review documenting confirmation of the pregnancy and the pregnancy outcome are undertaken. For implant users, in addition to the enrollment visit, venipuncture is offered annually (at the anniversary of the implant insertion), at the time of method removal, or if a pregnancy is experienced during implant use. Participants are compensated with a $40 gift card at enrollment, and $20 for completion of each survey, and for each venipuncture. At the time of venipuncture, 7 mL of whole blood are collected and allowed to sit upright for clot formation for 1–2 hours. Samples are then centrifuged for 10 minutes at 4° C at 3000 rpm. Serum is aliquoted off and stored in a laboratory freezer at −80° C. Samples are then sent to the Columbia University Medical Center Core Laboratory for etonogestrel analysis where liquid chromatography tandem mass spectrometry is performed by the Biomarkers Core Laboratory of the Irving Institute of Clinical and Translational Research at Columbia University Medical Center.[8] Participants are informed that the results from their ENG assay will not impact their eligibility for study continuation or their clinical care. Participants are asked to inform study staff at any time they suspect they may be pregnant or if they desire method removal. Method removal is provided without charge at any time to all participants.

Our primary outcome is unintended pregnancy during prolonged use. Pregnancy rates are presented in women-years of follow-up. Participants contributed to this analysis beginning at method expiration (end date of FDA-approved duration) until the last contact date, through 30 months post-expiration. Secondary outcomes include quantification of serum ENG levels at various time points during prolonged use of the implant and comparison of ENG levels across body mass index (BMI) classes. For ENG level assessment, we defined “year 3” to be any sample drawn from expiration through 6 months of additional use (3.5 years), a “year 4” sample to have been collected between 3.5 years and 4.5 years of use, and a “year 5” sample to have been collected between 4.5 and 5.5 years of use. Our cohort retention rate is 97.9% at 12 month and 94.8% at 24 months.

All statistical analyses were performed using SAS Software (v.9.4.; SAS Institute, Cary, NC). Significance levels (α) were set at 0.05. Demographic characteristics of all participants are presented as means, standard deviations and percentages. Unintended pregnancy rate was calculated using number of unintended pregnancies divided by total women years of follow-up and 95% confidence interval (CI) was calculated. Since there were zero pregnancies documented in the implant group during the follow-up period, a one-sided 97.5% CI was calculated. χ^2-square test and Fisher’s exact test were performed to examine the subjects’ characteristics differences across the three BMI groups. ENG levels were not normally distributed; thus, the Kruskal-Wallis test was used to compare the median etonogestrel levels across the three BMI categories at 3, 4, and 5 years of implant use.

Results

At the time of analysis, 291 implant users were enrolled in the EPIC study, contributing 444.0 women-years of time to this analysis. Of these users, 223 (77%) have used their method for greater than 12 additional months and 102(35%) for greater than 24 additional months. The mean durration of prolonged implant use is 18.9 additional months (range 0–44.1 months) This cohort includes 496 levenogestrel IUD users contributing 696.9 women-

years of time to this analysis. Of these users, 347 (70%) have used their method for greater than 12 additional months and 160 (32%) for greater than 24 additional months. The mean duration of prolonged IUD use is 19.3 additonal months (range 0.2–41.1 months).

Overall, the mean age of the entire study population (IUD and implant) was 29.9 years. Black women accounted for 58.5% (N=459) of the cohort with 35.7% (N=280) subjects reporting white race. The majority of the study population (96.7%, N=760) were non-Hispanic. Less than half of the subjects were categorized as low socioeconomic status (46.7%, N=367) and 49.9% (N=392) were single or never married. Comparison of the characteristics of the study population by method type are shown in Table 1. Compared to IUD users, implant users are younger, less educated, and more likely to be single and to report lower socioeconomic satatus. Participant BMIs ranged from 16.5 to 62.7. In our cohort, 25% (N=58) were of normal weight, 22% (N=55) were overweight, and 53% (N=127) were obese or morbidly obese. Patients with higher BMIs in our population were more likely to be older ($p = 0.02$), to have higher gravidity ($p < 0.01$), and to be of lower socioeconomic status ($p < 0.01$) (Table 2).

The 291 implant users contributed 157 year 3 samples, 143 year 4 samples, and 50 year 5 samples. We examined the association between ENG levels and BMI classes for each year of use. The median etonogestrel level at 3 years of use was 207.7 pg/mL (range 63.8–802.6 pg/mL), 166.1 pg/mL (range 25.0 – 470.5 pg/mL) at 4 years of use, and 153.0 pg/mL (range 72.1–538.8 pg/mL) at 5 years of use. We found no differences in median serum ENG levels across BMI groups at method expiration (P=0.10) or at the end of the fifth year of use (P= 0.62). We did find a significant difference in ENG levels by BMI after four years of use (P = 0.04); however, the trend was not linear with median levels in the overweight group higher than both the normal weight and obese groups. The median ENG levels for each BMI class at each year of use are shown in Figure 1. To date we have documented two pregnancies in the LNG IUD group. The failure rate in the sixth year of use (1 year post-expiration) is calculated as 0.25(%95 CI 0.04–1.42) per 100 women year; failure rate during the seventh year (2 year post expiration) is 0.43 (%95 CI 0.08–2.39) per 100 women years. In the cohort of implant users, we have documented zero pregnancies. We calculate failure rate in the fourth year of use to be 0 (onesided %97.5 CI 0–1.48) per 100 women year and the rate in the fifth year of use is 0 (one-sided %97.5 CI 0–2.65) per 100 women years.

Comment

Our findings continue to support effectiveness of the 52 mg levonorgestrel IUD and etonogestrel implant in preventing pregnancy for up to two additional years beyond their current FDA-approved durations of three and five years, respectively.

Our findings supplement the limited available data on prolonged use including a small Thai study that found zero pregnancies in 75 women who used the etonogestrel implant for four years. With an additional 411.7 woman years of use for an additional year, we have strengthened the evidence from our initial publication. Likewise, this cohort now includes more than 250 woman-years of use for 2 additional years, demonstrating continued efficacy and consistent with recent data published by the World Health Organization.[6]

Our previously published data from the EPIC study represented the first publication in the medical literature to correlate clinical pregnancy outcomes with pharmacokinetic measures of etonogestrel levels in implant users continuing to use their method beyond the FDA-approved duration. The median etonogestrel levels at each year remained well above 90 pg/mL, a previously published threshold for ovulation suppression. However, the absolute threshold of contraceptive effectiveness remains poorly defined and may be lower than 90 pg/mL as secondary mechanisms such as cervical mucus changes may prevent pregnancy should ovulation occur. In the future, we hope to evaluate the rate of decline of serum ENG levels as well as the amount of ENG that remains in the device at the time of removal. We also will assess suppression of ovulation in women continuing their method beyond the FDA-approved duration. These data would help to further define the clinical relevance of implant pharmacokinetics.

Our study also differentiates etonogestrel levels across women of varying BMIs at three, four, and five years of implant use. Previous pharmacokinetic data suggested that obese women have lower serum etonogestrel levels than their normal weight counterparts, but clinical data has not shown an increased pregnancy rate in this group.[9,10] Although we found that after four years of use, women with the highest BMIs had significantly lower ENG levels than women with lower BMIs, the clinical relevance is questionable given we did not find a linear trend in ENG levels by BMI. Furthermore, we saw no difference in ENG levels across BMI categories at five years of implant use, although our numbers are small. More importantly, our data indicate that median ENG levels at year 4 and 5 years of use remained above 90 pg/mL regardless of BMI class. Thus, we do not believe that women with elevated BMIs are at increased risk of contraceptive failure with extended implant use.

Our study supports prior publications indicating that the 52-mg levonorgestrel IUD can be used safely for up to seven years. Our failure rate of 0.25–0.43 per 100 women-years is comparable to the published failure rate during its current FDA-approved use period of five years, and is clearly superior to a pregnancy risk with use of the oral contraceptive pill, transdermal patch, or vaginal ring. Consistent with our findings, Sivin et al. randomized more than 2,000 women to a levonorgestrel-releasing IUD or a copper IUD and followed participants long-term. No pregnancies occurred with either device in years 6 or 7. The levonorgestrel device used in this study released 20 mcg/day, but was not identical to the 52mg LNG IUD used today.

Our study has several strengths. The EPIC study includes a large and diverse cohort of women that represent a spectrum of age, race, and socioeconomic status, supporting its generalizability to a larger population. This additional year of follow-up for implant users, we believe, represents the only published prospective data providing evidence of up to five years of efficacy in a U.S. population. As previously mentioned, very recent data in an international population has also demonstrated continued effectiveness for two additional years of use.[6] Unlike our study, this WHO study randomized women to either the single rod etonorgestrel implant or the two-rod levonogestrel implant. Their population was followed from the time if implant insertion, where as our cohort enrolled at the time of method expiration. Despite minor differences in methodology, the two studies confirm the same finding of continued effectiveness for an additional two years of use.

In addition to providing data for the fifth year of implant use, we have strengthened the evidence for four years of use with a larger and more robust cohort. Our study also draws on objective sources of data including height and weight measurements used to calculate BMI and a specific serum ENG assay findings for etonogestrel levels. Similarly, the size of our cohort of 52 mg LNG IUD users has increased at six and seven years, further increasing the precision of our estimates and supporting our prior findings and that of Sivin et al.

One limitation of our study is the relatively small numbers of ENG samples we have at five years of implant use. We may not yet have the power to detect small differences among BMI classes at five years of use. We are reassured, however, by the median ENG levels that remain well over the 90 pg/mL mark for all BMI categories and that we have had no pregnancies in any group. A final limitation is that we used self-report to document contraceptive failures. While we validated positive reports whenever possible, it is possible that women may under-report unintended pregnancies due to social desirability bias.

In conclusion, our continued follow-up of woman using their contraceptive implants and levonorgestrel IUDs after the FDA-approved duration of three and five years, respectively, strengthened our previous findings that the etonogestrel implant and levonorgestrel IUD can be safely used for an additional year, and provides evidence that they can be used for two additional years. Our data suggests that the implant and the LNG IUD each maintain their contraceptive effectiveness for at least an additional two years. Etonogestrel levels are maintained above the contraceptive threshold of 90 pg/ml in all BMI classes at 3, 4, and 5 years.

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Condensation

The subdermal etonogestrel contraceptive implant and the 52mg levonorgestrel intrauterine device effectively prevent pregnancy for two additional years beyond the FDA-approved duration.

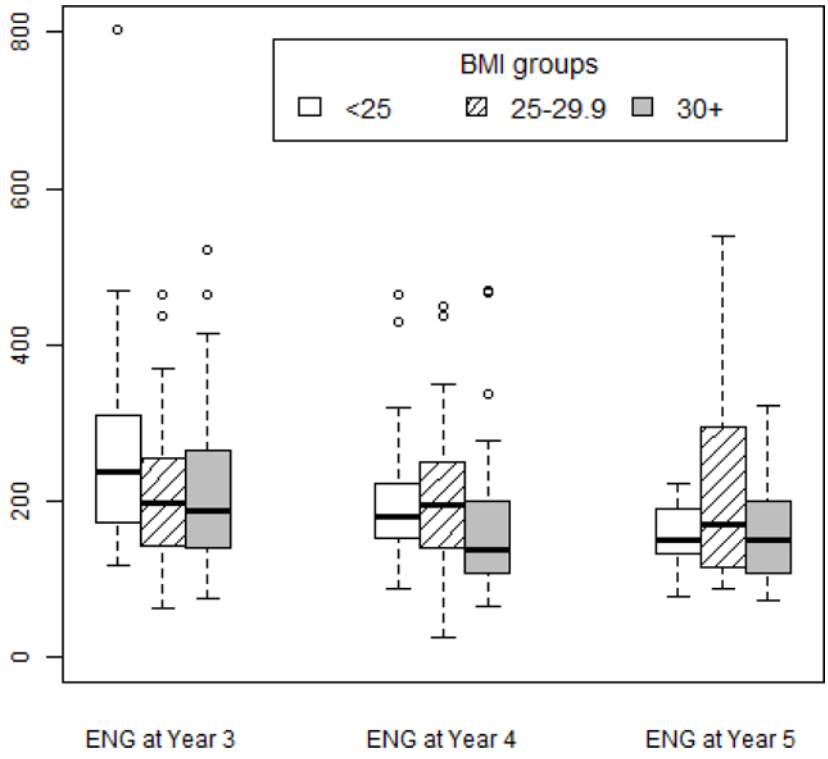

Figure 1.
Median Etonogestrel (ENG) Levels at Years 3, 4 and 5 by Body Mass Index (BMI) Categories

Table 1

Baseline Demographic and Reproductive Characteristics of Implant and LNG IUD Users

Characteristic	Implant (n=291)	IUD (n=496)	P
Age (y), n (%)			< .001
18–22	90 (30.9)	7 (1.4)	
23–29	138 (47.4)	186 (37.5)	
30–34	33 (11.3)	140 (28.2)	
35–45	30 (10.3)	163 (32.9)	
Race[†], n (%)			<.001
Black	205 (70.4)	254 (51.4)	
White	63 (21.6)	217 (43.9)	
Other	23 (7.9)	23 (4.7)	
Ethnicity[*], n (%)			0.16
Hispanic	13 (4.5)	13 (2.6)	
Non-Hispanic	278 (95.5)	482 (97.2)	
Education, n (%)			<.001
High school or less	99 (34.0)	92 (18.5)	
Some college or vocational school	154 (52.9)	184 (37.1)	
Completed college or greater	38 (13.1)	220 (44.4)	
Medical insurance status[*], n (%)			<.001
None	103 (35.5)	132 (26.6)	
Medicare/Medicaid	63 (21.7)	77 (15.5)	
Private	124 (42.8)	287 (57.9)	
Low socioeconomic status[*], n (%)			<.001
Yes	172 (59.1)	195 (39.4)	
No	119 (40.9)	300 (60.6)	
Marital status[*], n (%)			<.001
Single or never married	189 (64.9)	203 (41.0)	
Married or cohabitating	96 (33.0)	254 (51.3)	
Separated/Divorced/Widowed	6 (2.1)	38 (7.7)	
Gravidity[ǂ] n (%)			0.16
0	83 (28.7)	144 (29.6)	
1–2	128 (44.3)	185 (38.0)	
3 or more	78 (27.0)	158 (32.4)	
BMI[†], n (%)			0.07
Less than 25	73 (25.1)	162 (32.8)	
25–30	67 (23.0)	106 (21.5)	
30 or higher	151 (51.9)	226 (45.7)	

BMI, body mass index.

[*] Data missing for one participant

[†] Data missing for two participants

[‡] Data missing for eleven participants

[**] Low socioeconomic status is defined as any participant reporting difficulty paying for basic needs such as food shelter or childcare or receiving public assistance.

Table 2

Demographic Characteristics by Body Mass Index (BMI) of Implant Users Contributing ENG Levels

Characteristic	BMI			P
	Less than 25 (n=58)	25–30 (n=55)	30 or higher (n=127)	
Age (y), n (%)				0.02
18–22	23 (39.7)	23 (41.8)	26 (20.5)	
23–29	26 (44.8)	26 (47.3)	65 (51.2)	
30–34	5 (8.6)	4 (7.3)	22 (17.3)	
35–45	4 (6.9)	2 (3.6)	14 (11.0)	
Race, n (%)				0.10
Black	36 (62.1)	38 (69.1)	100 (78.7)	
White	18 (31.0)	11 (20.0)	19 (15.0)	
Other	4 (6.9)	6 (10.9)	8 (6.3)	
Ethnicity, n (%)				0.05
Hispanic	1 (1.7)	6 (10.9)	4 (3.1)	
Non-Hispanic	57 (98.3)	49 (89.1)	123 (96.9)	
Education, n (%)				0.45
High school or less	14 (24.1)	19 (34.5)	47 (37.0)	
Some college or vocational school	35 (60.3)	30 (54.5)	68 (53.5)	
Completed college or greater	9 (15.5)	6 (10.9)	12 (9.4)	
Medical insurance status, n (%)				0.40
None	18 (31.0)	18 (34.6)	47 (38.8)	
Medicare/Medicaid	8 (13.8)	12 (23.1)	25 (20.7)	
Private	32 (55.1)	22 (42.3)	49 (40.5)	
Low socioeconomic status, n (%)				0.002
Yes	23 (39.7)	35 (63.6)	84 (66.1)	
No	35 (60.3)	20 (36.4)	43 (33.9)	
Marital status, n (%)				0.73
Single or never married	40 (69.0)	40 (72.7)	85 (66.9)	
Married or cohabitating	16 (27.6)	15 (27.3)	40 (31.5)	
Separated/Divorced/Widowed	2 (3.4)	0 (0.0)	2 (1.6)	
Gravidity*, n (%)				0.005
0	24 (41.4)	20 (37.0)	24 (18.9)	
1–2	25 (43.1)	21 (38.9)	59 (46.5)	
3 or more	9 (15.5)	13 (24.1)	44 (34.6)	

* Data missing for one participant

** Low socioeconomic status is defined as any participant reporting difficulty paying for basic needs such as food shelter or childcare or receiving public assistance.