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Plasma levonorgestrel levels in women using LNG20, a new levonorgestrel intrauterine system, and Mirena

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LEVONORGESTREL RELEASE RATES WITH LNG20, A NEW LEVONORGESTREL INTRAUTERINE SYSTEM, AND MIRENA

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Objectives: To compare the in vitro release rates of LNG20, a new levonorgestrel intrauterine system (LNG-IUS) and a marketed LNG-IUS Mirena®.

Method: The release rate performance of seven LNG20 and seven Mirena IUS products, each with a reservoir length of 20 mm surrounded by a release rate controlling membrane, were assessed in an in vitro diffusion test in sink conditions for approximately 3 years (1100 days). An early prototype of this LNG releasing system using exactly the same technology as the LNG20 but with a slightly thicker membrane was also compared to Mirena ($n=3$ and 5, respectively) over approximately 5 years (1850 days) using the same diffusion testing.

Results: The initial release rates of LNG20 and Mirena are both approximately 20 mcg/day. The rates decline over the first few days and plateau at approximately 16–17 mcg/day at about 2 weeks. The release rates decline slowly to approximately 13 mcg/day at 3 years. This time course is linear (zero-order release) over this extended duration. The calculated amount of LNG left in both systems at the end of this period is approximately 36 mg compared with the starting amount of 52 mg. The early LNG releasing system prototype shows a slightly lower diffusion rate but the same linear time course over 5 years.

Conclusions: The in vitro release rates of LNG20 and Mirena are similar over 3 years.

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KNOWLEDGE OF CONTRACEPTIVE EFFECTIVENESS AMONG A COHORT OF ST. LOUIS WOMEN CHOOSING REVERSIBLE CONTRACEPTION

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Objectives: Determine whether women enrolled in the Contraceptive CHOICE Project (CHOICE) have prior understanding of the effectiveness of their chosen contraceptive method.

Method: CHOICE is an ongoing prospective cohort study of 10,000 women 14–45 years old. Among the first 2500 enrolled, 1557 women completed a contraceptive knowledge questionnaire prior to receiving contraceptive counseling and choosing their method. For each contraceptive method, women were asked “what percentage would get pregnant in a year: <1%, 1–5%, >6–10%, >10% and don’t know.”

Results: Fifty-seven percent of participants chose intrauterine contraception (IUC), 12% implant, 7% depo-medroxyprogesterone acetate (DMPA), 24% pill/patch/ring. Participants had a mean age of 25 years (S.D.=5.7), mean age at first intercourse of 16.3 years (SD=2.4), 30% reported a history of sexually transmitted infection, 90% have had ≥ 2 lifetime sexual partners. Ninety-four percent of women who have been pregnant reported an unintended pregnancy. Overall, 87% of subjects knew the annual risk of pregnancy was >10% if no contraception is used. Women who chose IUC (74%) were more likely to correctly estimate the effectiveness of their selected method versus implant (47%), DMPA (28%), or pill/patch/ring choosers (16%); $p<.01$, even after adjusting for age and education (RR 1.3, 95% CI 1.2–1.4). The most common mistake, for all participants, was overestimating the effectiveness of their chosen method.

Conclusions: Though sexually experienced and aware of the risk of pregnancy, this cohort demonstrated significant knowledge gaps regarding contraceptive effectiveness. Women who selected IUC had greater prior

knowledge of the effectiveness of their chosen method than women who selected other methods.

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PLASMA LEVONORGESTREL LEVELS IN WOMEN USING LNG20, A NEW LEVONORGESTREL INTRAUTERINE SYSTEM, AND MIRENA

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Objectives: Plasma levonorgestrel levels were evaluated for equivalence in women with menorrhagia using LNG20, a new levonorgestrel intrauterine system (LNG-IUS), and a marketed LNG-IUS Mirena® over 6 months.

Method: As part of a clinical study to compare LNG20 and Mirena for menorrhagia treatment, 211 women ($n=109$ and 102, respectively) were enrolled in a planned substudy to evaluate levonorgestrel levels. Plasma samples were drawn at baseline and weeks 1, 2, 4, 13 and 24. An analysis of covariance model was used to estimate mean differences and to determine equivalence. Equivalence claims are based on the 95% confidence interval (CI) of the least square (LS) mean difference falling within a set non-inferiority interval (–10 ng/L, 10 ng/L). Plasma levels (ng/L) are presented as mean \pm S.D.

Results: The 95% CI for the LS mean difference was (–9.45 ng/L,+4.72 ng/L), within the non-inferiority interval. Mean concentrations at each visit were similar ($p>.05$). Plasma levels for LNG at weeks 1, 2, 4, 13 and 24 for LNG20 were as follows: 131 \pm 51, 131 \pm 53, 126 \pm 51, 127 \pm 49, and 125 \pm 49. Plasma levels for Mirena were 145 \pm 63, 145 \pm 59, 135 \pm 57, 128 \pm 54, and 125 \pm 42, respectively.

Conclusions: LNG20 and Mirena produced equivalent plasma levonorgestrel levels in women with menorrhagia over the first six months of use.

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CONTINUATION AND SATISFACTION OF REVERSIBLE CONTRACEPTION: A PRELIMINARY ANALYSIS FROM THE CONTRACEPTIVE CHOICE PROJECT

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Objectives: The primary objectives of the Contraceptive CHOICE Project are to promote the use of long-acting reversible methods of contraception (LARC) and to determine continuation rates and levels of satisfaction with all reversible methods.

Method: The CHOICE Project has enrolled over 5000 sexually active women in the St. Louis region who are willing to try a new reversible contraceptive method. Participants between the ages of 14 and 45 are enrolled and followed for 3 years with phone interviews at 3 and 6 months and every 6 months thereafter. All contraceptive methods are provided at no cost. We analyzed the results of the first 2076 women enrolled who have complete data at least through the 12-month interview.

Results: Among the first 5,092 women enrolled in CHOICE, 69.9% have chosen a LARC method [57.5% intrauterine contraception (IUC) and 12.4% implants]. LARC users had higher 12-month continuation rates (87% v. 73%; RR=1.2, 95% CI 1.1, 1.3) and were more likely to be somewhat or very satisfied with their method of contraception than pill users (85% versus 73%; RR=1.2, 95% CI 1.1, 1.3). At 1 year, there was no difference in continuation rates or satisfaction between the copper and levonorgestrel IUC. However, all other reversible contraceptive methods had lower 12-month satisfaction than IUCs (69% vs. 87%; RR=0.80, 95% CI 0.76, 0.84).

Conclusions: LARC method users had the highest levels of continuation and satisfaction. IUCs and subdermal implants should be first