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The levonorgestrel intrauterine system: cohort study to assess satisfaction in a postpartum population in Kenya

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Abstract

Background: The levonorgestrel intrauterine system (LNG IUS) may become the next long-acting contraceptive to be introduced in public sector programs of resource-poor countries. Whereas service provision for subdermal implants and intrauterine devices is growing, little is known about how the LNG IUS might fit in.

Study design: We conducted a cohort study of 313 women in Kenya who were 6–12 weeks postpartum when they started using these methods: subdermal implant (205), LNG IUS (93), and copper intrauterine device (15). Participants returned for visits at 6 and 12 months to share information on bleeding patterns, side effects, satisfaction, and continued use of the products. We used Kaplan–Meier techniques to estimate method continuation rates and chi-square tests of association to identify differences in experiences with the methods.

Results: The 12-month continuation rate for the LNG IUS was 89.1 (95% confidence interval [CI] = 86.9–94.9) and statistically equivalent to that of the subdermal implant (91.8: 95% CI = 80.6–94.0). Nearly 87% of LNG IUS users were very satisfied with the method at 6 months compared to 75% of implant users; this gap closed somewhat at 12 months as satisfaction levels of implant users rose. At 12 months 78% of LNG IUS users felt that their bleeding pattern was highly acceptable compared with about 66% of implant users.

Conclusions: This study found that the LNG IUS compared favorably to the subdermal implant in terms of satisfaction levels and continued use. The LNG IUS will provide another long-acting option for postpartum women.

Implications: The LNG IUS may soon be purchased by international donor agencies for use in public sector programs in sub-Saharan Africa and other resource-poor countries. The results of this study suggest that the product will be successful in future introduction activities.

Keywords: Levonorgestrel intrauterine system; Acceptability; Continuation rates; Africa; Comparison; Long-acting reversible contraception

1. Introduction

Subdermal implants and intrauterine devices (IUDs) are products in the category known as long-acting reversible contraception (LARC). LARC is the most effective temporary (spacing) family planning option [1], provides between 3 and 10 or more years of protection, and is safe to use in the postpartum period [2]. These family planning methods are indispensable technologies, particularly in settings where sterilization services are not widespread. More LARC choices may help postpartum women prevent short birth intervals.

The levonorgestrel intrauterine system (LNG IUS) may be an ideal LARC method for postpartum women who have yet to return to normal menstrual cycles. Initiation of the LNG IUS in this time may avoid disturbances that can lead to early removal if started during other times. Because the LNG IUS releases levonorgestrel into the uterus, the systemic effects are not as pronounced as perhaps other hormonal methods; side effects may be more tolerable for many users compared with other methods. In addition, the LNG IUS decreases menstrual blood loss, which in turn increases hemoglobin and ferritin levels [3]; this mechanism may help anemic women recover from childbirth more quickly.

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Like other contraceptives, the LNG IUS does not appear to affect breastmilk or infant growth [4].

In Europe and the United States, the commercial LNG IUS has become very popular [5,6]. In resource-poor countries, only the highest socioeconomic classes can afford to buy it. A nonprofit foundation has helped more than 50,000 lower socioeconomic women in resource-poor countries get the LNG IUS product free of charge [7]. In Ghana and Kenya, uptake and views of the product have been positive [8,9]. Several lower-cost LNG IUS are now available [10–11]. These advances may eventually lead to more widespread use of the LNG IUS in resource-poor settings.

We undertook this project to assess how the LNG IUS might complement existing LARC options in a postpartum population. Specifically, we compared the subdermal implant, the copper IUD, and the LNG IUS in terms overall acceptability and product retention, with the goal of informing future decisions on expanding access.

2. Material and methods

We conducted a prospective cohort study of LARC in Nairobi, Kenya, and recruited recent postpartum women. Women were recruited at the Mathare North health center (operated by the Nairobi City Council and Kenyan Ministry of Health) from July 2011 to May 2012. (This public sector facility is part of a network that serves marginalized populations in the metropolitan area of Nairobi.) Participants enrolled voluntarily through an informed consent process that was approved by the Protection of Human Subjects Committee (of FHI 360) and the Kenya Medical Research Institute's Ethical Review Committee.

We described the enrollment details in an earlier publication [9]. Briefly, women were eligible for the study if they were 6–12 weeks postpartum, 18–39 years of age, seeking a family planning method, living in the clinic area, and having access to a phone. Women choosing a LARC method entered the 12-month cohort study and were told they could have the contraceptive removed at any time and for any reason.

The LNG IUS product was donated by the International Contraceptive Access (ICA) Foundation [7]. The product is essentially the same as the commercial product used throughout Europe and in the United States. It contains 52 mg of levonorgestrel that is released from a reservoir on the vertical stem of the polyethylene device. The main difference between the commercial product and the LNG IUS is the inserter; the LNG IUS uses the older-style, two-handed, linear inserter, whereas the commercial product uses a curved, one-handed inserter and "slider" technology on the handle for placing the product in the uterus. The other LARC products were a copper IUD (the TCu380A) and the two-rod levonorgestrel subdermal implant marketed as Jadelle®.

At admission, we collected standard sociodemographic information, data on past pregnancies and future plans, and previous contraceptive method use. Participants were asked to return at 6 and 12 months after insertion to share information on bleeding patterns, satisfaction with their method, and to record any product removal events. We collected the same follow-up information at any unscheduled visits as well. The data for this study were double-entered in EpiData software, and all analyses were done using SAS.

To estimate contraceptive continuation rates, we calculated "days on product" using the last follow-up date with the contraceptive in situ. Some women had the products removed elsewhere before the visit, and the removal date was used in the calculations. Kaplan–Meier techniques were used to estimate 12-month continuation rates, and 95% confidence intervals (CIs) were calculated with a logarithmic transformation. We asked participants the reasons for removal. Follow-up was completed in 2013.

To compare how the products affect bleeding patterns, induce side effects, and affect overall acceptability, we examined 6- and 12-month data separately. We defined the 6-month window as ±2 weeks (168 to 196 days) and the 12-month window as ±1 month (334 to 396 days). We calculated percentage distributions and used chi-square tests of association and Fisher's Exact Tests as appropriate.

Because of attrition due to early removal, side effects and satisfaction can appear to improve over time in a prospective study. Dissatisfied users often stop using a product, leaving an increasingly satisfied population under observation and contributing data; these actions introduce bias. To adjust for this potential problem, we did additional (confirmatory) analyses using techniques referred to as "last observation carried forward". Thus, the last recorded side effects and satisfaction measures for participants who had their product removed before the 6- and 12-month windows were used. This technique added one observation for the 6-month analysis and 13 observations for the 12-month analysis.

3. Results

The complete cohort consisted of women using the following methods: subdermal implant (n = 205), LNG IUS (n = 93), and copper IUD (n = 15). (Because of low uptake, results for copper IUD users will not be reported.) In our previous paper, we reported the methods that participants selected; however, some women never started those methods for the cohort study (some for medical contraindications and others for personal reasons). Subdermal implant users and LNG IUS users were similar in terms of baseline characteristics (Table 1). Fifty percent of implant users and nearly 40% of LNG IUS acceptors reported that their last pregnancy was unintended. LNG IUS users appeared to have slightly higher education levels ($p < .05$).

Ten participants were completely lost-to-follow-up (nine in the implant group and one in the LNG IUS group never