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A comparative study of the levonorgestrel-releasing intrauterine system Mirena® versus the Copper T380A intrauterine device during lactation: breast-feeding performance, infant growth and infant development

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Abstract

Background: Mirena® is a levonorgestrel-releasing intrauterine system (LNG-IUS) that provides highly effective and long-acting progestogen-only contraception.

Objective: The objective of this study was to analyze the possible effects of using LNG-20 μg IUS on breast-feeding performance, infant growth and infant development during the first postpartum year as compared with the Copper T380A intrauterine device (Cu T380A IUD).

Design: This study is a prospective, controlled and randomized trial.

Setting: The study was conducted at the Department of Obstetrics and Gynecology, Assiut University Hospital, Egypt.

Methods: Three hundred twenty lactating women asking for initiation of contraception during the early postpartum stage were assigned randomly into two groups, the LNG-20 μg IUS group ($n=163$) and the Cu T380A group ($n=157$). The insertions were done 6–8 weeks postpartum. Each participant was followed up at three monthly intervals after insertion and until the first birthday of her baby. During these visits, the breast-feeding pattern was assessed, certain infant physical growth parameters were measured and a set of infant development tests was performed.

Results: No pregnancy occurred in both groups. There were no significant differences in the net continuation rates between the two groups (89.3 for LNG-IUS vs. 90.9 for Cu T380A). The LNG-20 μg IUS group had comparable rates of breast-feeding continuation, complete weaning, full breast-feeding and partial breast-feeding, with the Cu-IUD group. No statistically significant differences were found between groups with regard to all infant physical growth parameters and various infant development tests.

Conclusion: The findings of the current study confirm that the use of LNG-20 μg IUS during the first postpartum year in lactating women provides highly effective and acceptable contraception and does not negatively influence breast-feeding or the growth and development of breast-fed infants.

Keywords: Levonorgestrel-releasing intrauterine system; Breast-feeding; Infant growth and development

1. Introduction

Each year, more than 100 million women make decisions about beginning contraception after childbirth. Choices for contraception may be limited for lactating women due to concerns about hormonal effects on quality and quantity of milk, passage of hormones to infants and infant growth [1]. According to the data of a recent Egyptian demographic and health survey, approximately 80% of Egyptian women breast-fed for at least 6 months and 40% breast-fed for up to18 months. Thirty-six percent of mothers with children younger than 6 months were exclusively breast-feeding and amenorrheic, but only 4% reported relying on breast-feeding for family planning [2].

A number of progestogen-only contraceptives have been shown not to influence breast-feeding or the growth and development of breast-fed infants. These methods include the following: progestogen-only pills (POPs), depot-medroxyprogesterone acetate (DMPA) injectables, norethisterone enanthate (NET-EN) injectables and subdermal contraceptive implants releasing levonorgestrel (LNG; Norplant®) [3,4]. However, it is suggested that implants that release orally inactive progestin (e.g., nestorone and elcometrine) represent an advantage since infants should be free of steroidal effects [5].

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LNG-releasing intrauterine systems (LNG-IUSs) release LNG locally in the endometrium at very high concentrations that are more than 1000-fold greater than serum levels [6]; atrophic changes in the endometrium markedly limit endometrial LNG uptake [7]. Only 0.1% of the serum dose of LNG can be transferred via milk to nursing infants [8]. LNG-IUSs are long-acting progestogen-only contraceptives, rapidly reversible and deliver the lowest daily dose of hormones (10–30 μg/24 h) [9,10]. Actually, the plasma concentrations achieved by LNG-IUS are lower than those seen with Norplant® and LNG minipills [11–13].

In his pioneer study, Heikkilä [10] tested the safety of LNG-IUS releasing 10 and 30 μg per 24 h inserted 6 weeks postpartum on breast-feeding duration, infant growth and infant development. He concluded that LNG measured in milk is very low and no harmful effects on breast-feeding or infant growth were observed. However, to date, evidence from randomized controlled trials on the effect of hormonal contraceptives during lactation is limited and inadequate to make clear recommendations. More properly conducted randomized controlled trials of adequate size are still needed to address this question [1].

The present study was designed to evaluate the possible effects of an LNG-IUS (Mirena®) that releases 20 μg/day on breast-feeding performance and infant growth and development during the first postpartum year.

2. Subjects and methods

2.1. Study design and subject selection

This is a prospective, controlled and randomized trial of LNG-20 μg IUS (Mirena®) and the Copper T380A intrauterine device (Cu T380A IUD). It was conducted at the Department of Obstetrics and Gynecology, Assiut University Hospital, Egypt. During the period June 2001–June 2003, a total of 320 exclusively breast-feeding women requesting contraception during the second month postpartum was enrolled. All women had given birth to healthy term babies without any health problem and had no contraindications to the use of LNG or Cu IUD contraceptives. They were planning to breast-feed for at least 1 year.

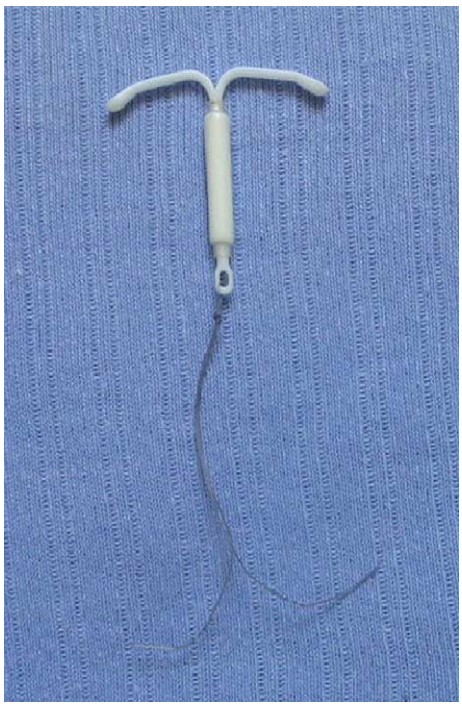

Fig. 1. The Levonorgestrel Releasing Intrauterine System, Mirena®.

Table 1
Characteristics of participants at admission (mean±SD)

Parameter	LNG-IUS (Mirena®) group (n=163; mean±SD)	Cu T380A IUD group (n=157; mean±SD)	p
Age (years)	26.6±5.1	25.3±5.5	.06
Weight (kg)	67.3±13.3	65.8±12.4	.32
Height (cm)	159.5±4.2	159.5±7.4	.77
Parity	3.0±2.2	2.8±2.3	.53
Education (years)	9.1±5.5	7.9±5.8	.06
	n (%)	n (%)	p
Residence			
Rural	81 (49.7)	85 (54.1)	.42[a]
Urban	82 (50.3)	72 (45.9)	
Infant sex			
Male	89 (54.6)	96 (61.1)	.73[a]
Female	74 (45.4)	61 (38.9)	

Two-tailed Student's t test for unpaired data was used.
[a] Pearson's χ^2 test was used.

A randomization scheme was used to assign participants to either of the study groups. The randomization was administered using a computer-generated series of sequential numbers. The allocations were put in sealed opaque envelopes containing the group assignments and were opened in sequential order at the time each participant was admitted into the study. According to the randomization scheme, 163 participants were enrolled in the LNG-20 μg IUS group and 157 participants were enrolled in the Cu T380A group.

Ethical clearance for the study was obtained from the medical ethics board of the School of Medicine, Assiut University, Egypt.

2.2. Sample size

Previous studies suggested that the breast-feeding rate in Assiut, Egypt, for the first postpartum year could be as

Table 2
Admission characteristics of the infants

Characteristic	LNG-IUS (Mirena®) group (n=163; mean±SD)	Cu T380A group (n=157; mean±SD)	p
Age (days)	46.9±6.9	47.4±7.7	.56
Weight (g)	4796±595	4710±631	.32
Length (cm)	55.4±3.5	55.1±3.0	.34
Head circumference (cm)	37.3±1.6	37.5±1.4	.30
Mid-arm circumference (cm)	11.3±1.0	11.5±1.1	.22
Skin-fold thickness (mm)	7.0±1.3	7.2±5.9	.69

Two-tailed Student's t test for unpaired data was used.