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Original research article

Timing of postpartum etonogestrel-releasing implant insertion and bleeding patterns, weight change, 12-month continuation and satisfaction rates: a randomized controlled trial☆

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ABSTRACT

Objectives: To evaluate whether timing of etonogestrel (ENG) implant insertion during the postpartum period affects maternal bleeding patterns, body mass index (BMI) and 12-month satisfaction and continuation rates.
Study design: This is a secondary analysis of an open, randomized, controlled trial. Postpartum women were block-randomized to early (up to 48 h postpartum) or delayed (6 weeks postpartum) insertion of an ENG implant. Bleeding patterns and BMI were evaluated every 90 days for 12 months. At 12 months, we measured implant continuation rates and used Likert and face scales to measure users' satisfaction. The level of significance was 0.4% (adjusted by Bonferroni test for multiplicity).
Results: We enrolled 100 postpartum women; we randomized 50 to early and 50 to delayed postpartum ENG implant insertion. Bleeding patterns were similar between groups. Amenorrhea rates were high in both groups during the follow-up (52%–56% and 46%–62% in the early and delayed insertion group, respectively). Prolonged bleeding episodes were unusual in both groups during the follow-up (0–2%). Maternal BMI was similar between groups and decreased over time. Twelve-month continuation rates were similar between groups (early insertion: 98% vs. delayed insertion: 100%, p=.99). Most participants were either very satisfied or satisfied with the ENG implant in both groups (p=.9).
Conclusion: Women who underwent immediate postpartum insertion of the ENG implant have similar bleeding patterns, BMI changes, and 12-month satisfaction and continuation rates compared to those who underwent delayed insertion.
Implications: Our results from a secondary analysis of a clinical trial support that satisfaction, continuation and bleeding patterns do not differ when women received contraceptive implants immediately postpartum or at 6 weeks. However, the emphasis on infant growth in the trial and easy access to delayed placement may have influenced results.

1. Introduction

Unmet contraceptive needs remain high among postpartum women [1]. Immediate postpartum initiation of long-acting reversible contraceptives (LARCs), i.e., contraceptive implant and intrauterine devices, has been promoted to reduce unplanned pregnancies in this group [2].

The etonogestrel (ENG) contraceptive implant has high continuation rates when initiated immediately postpartum [3–6]. Immediate postpartum insertion of the ENG implant does not affect time to stage II lactogenesis, breast milk quantity and quality, exclusive breastfeeding rates, infant growth and some maternal outcomes such as coagulation profile [7–10]. According to a meta-analysis comparing immediate versus delayed ENG implant insertion, implant initiation rates were higher in the immediate group, but continuation rates at 6 months postpartum did not differ between groups. It was unclear whether there were any differences in 12-month continuation rates, side effects (e.g., bleeding patterns and weight gain) and satisfaction [11].

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Effective contraceptive counseling should help women identify method attributes, which leads to informed decision making and may improve continuation and satisfaction [12]. Unfavorable bleeding patterns are the main reason for ENG implant discontinuation [13,14]. Therefore, it is important to counsel prospective users about expected bleeding patterns with the ENG implant [14–16]. Weight gain is another important reason cited by women for discontinuing contraceptives [17].

In this secondary analysis, we investigated whether timing of postpartum ENG implant insertion affected bleeding patterns, body mass index (BMI), 12-month continuation and satisfaction rates. Our results may improve the anticipatory guidance to women interested in postpartum insertion of the ENG implant.

2. Methods

2.1. Study design

This was a secondary analysis of an open, randomized, controlled and parallel trial of early versus delayed postpartum insertion of the ENG implant for which the primary outcome was infant growth [7]. This analysis focused on postpartum women's outcomes.

We conducted the trial in the Women's Health Reference Center of Ribeirão Preto, a maternity ward affiliated with the University Hospital of Ribeirão Preto School of Medicine of the University of São Paulo, Brazil.

These institutions' ethical committees approved the study, which was registered on the Clinical Trials website (www.clinicaltrials.gov; NCT02469454).

2.2. Participants, intervention and randomization

We included postpartum women 18 years or older who selected the ENG implant for contraception and who did not have contraindications to breastfeeding or any clinical conditions category 3 or 4 for implant use according to the 2009 World Health Organization (WHO) criteria [18].

Participants were block-randomized into one of two arms: (1) early insertion group, in whom ENG-releasing implants (Implanon®, N.V. Organon, Oss, Netherlands) were inserted within 48 h of delivery, and (2) delayed insertion group, in whom the ENG implants were inserted at 6 weeks postpartum.

Details of the eligibility criteria and the randomization process were published previously [7].

2.3. Sample size

Postpartum women's outcomes were a secondary analysis. The sample size was calculated for the trial's primary outcome, which was infant weight at 12 months of age [7].

2.4. Outcomes and assessments

The outcomes for this analysis were maternal bleeding patterns and BMI, and method satisfaction and continuation rates.

Participants were followed for 12 months postpartum by in-person visits every 90 days. We completed a baseline visit on the day of randomization (within 48 h of delivery), during which we weighed participants, gave them bleeding diaries and taught them how to fill them out. We also inserted the ENG implant in postpartum women randomized to early insertion and instructed those randomized to delayed insertion to return 6 weeks later for implant insertion. At each 90-day visit, we recorded clinical complaints, reviewed diaries and weighed participants. We retained the diary from the previous visit and gave a new one for the following 90-day period. If participants had any adverse effects or if they wanted to remove the implant, they were seen within 7 days.

We developed a simplified paper bleeding diary in which participants recorded the number of bleeding/spotting (B/S) episodes they experienced (translated version available as online supplemental file). We did not differentiate bleeding from spotting, and both were considered bleeding. Participants started filling the diary at randomization. We instructed participants on how to recognize bleeding episodes and to record them in the diary. A bleeding episode was characterized by any B/S days bounded on either end by 2 days of no B/S [19]. Also, participants were instructed to record if any episode lasted more than 14 days. We did not evaluate the number of B/S days and bleeding volume.

Bleeding related to postpartum lochia was recorded but not considered as a bleeding episode in the analysis. We instructed participants that lochia begins at postpartum day 1 and generally lasts less than 8 weeks [20]. They were instructed to consider continuous bleeding from postpartum day 1 as lochia. Any bleeding that happened after 2 days without lochia was considering nonlochia and counted as a bleeding episode.

Bleeding patterns were classified based on the WHO's terminology using the frequency and duration of B/S episodes in a 90-day reference period (RP) [14,21], i.e., amenorrhea (no B/S episodes), infrequent (<3 B/S episodes), normal frequency (3–5 B/S episodes, representing the frequency of bleeding episodes expected in women with regular cycle) or frequent (>5 B/S episodes). The duration of a bleeding episode was defined as prolonged if it lasted >14 days [14,21]. We extracted the frequency of bleeding episodes as well as the frequency of prolonged bleeding episodes from the study diaries.

We measured participants' BMI at the baseline visit and then again 90, 180 and 360 days later.

We measured implant continuation rates based on the number of participants who were using the implant at 360 days of enrollment. In case of study discontinuation, we confirmed that the implant was not removed by a phone call to the participant, to an authorized family member or to the healthcare provider from the participant's primary care unit.

We measured users' satisfaction at 360 days of enrollment using two scales: a face scale and a Likert scale. Both were five-point scales ranging from “very satisfied” to “very dissatisfied.”

2.5. Statistical analyses and blinding

We used χ^2 and Fisher's Exact Tests for categorical variables. For quantitative demographic variables, we used Student's t test. We used a mixed-effects linear regression model to evaluate BMI. The level of significance was 5% for baseline clinical and demographic characteristics. For the outcomes analyzed in this study, the level of significance was corrected for multiple hypothesis testing using the Bonferroni adjustment. The adjusted level of significance was 0.4%.

We conducted intention-to-treat (ITT) and per-protocol (PP) analyses of bleeding patterns. In the ITT analysis, we included missing data. In the PP analysis, we excluded missing data. Each reference period in the PP analysis contained data from participants who were in the study and completed the bleeding diary for that RP.

To evaluate the association between exclusive breastfeeding and amenorrhea, we performed a subanalysis of women in the PP analysis in RP 1 and 2. We compared amenorrhea rates in exclusively breastfeeding women with nonexclusively breastfeeding ones. We previously described these groups' exclusive breastfeeding rates up to 6 months [7].

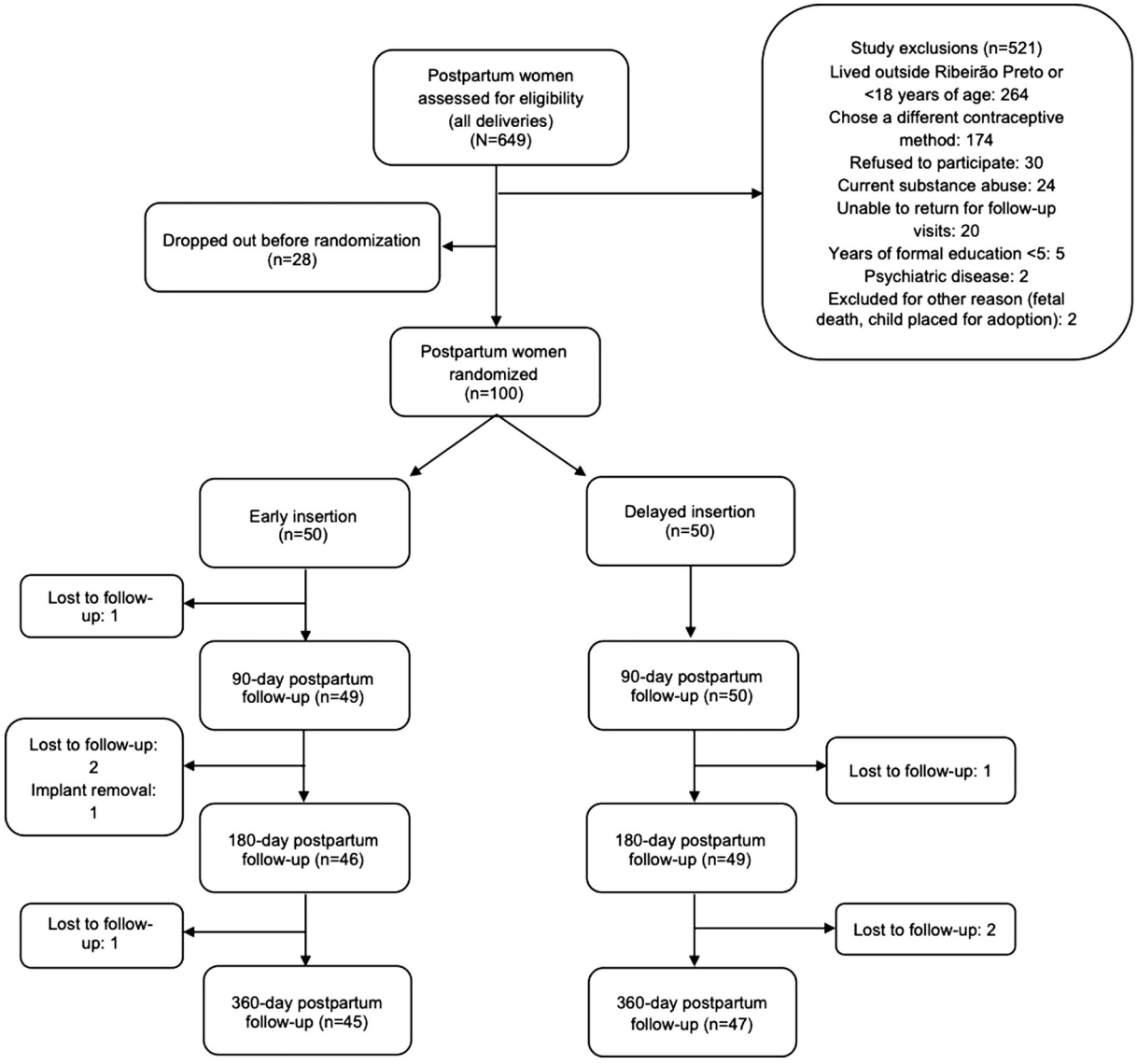

Fig. 1. Flowchart of the study. Early represents etonogestrel implant inserted within 48 h of delivery. Delayed represents etonogestrel implant inserted at 6 weeks postpartum.

We imputed BMI missing data using the last observation carried forward method.

For measures of satisfaction, we only analyzed data for the women who remained in the study and filled out the satisfaction forms. We evaluated the agreement between satisfaction scales using a weighted kappa agreement coefficient.

We used SAS 9.2 for all analyses (SAS Institute Inc., Cary, NC, USA). The statistician was blinded to the study groups.

3. Results

From June 10th to August 15th of 2015, we interviewed 649 postpartum women. Of these, 521 women did not meet eligibility criteria, 28 dropped out of the trial prior to randomization, and 100 were randomized (50 to early and 50 to delayed postpartum ENG implant insertion). During the follow-up, eight participants discontinued the study. One woman requested removal of the implant for personal reasons unrelated to any implant effect, and seven were lost to follow-up after five attempts of phone contact, although they continued using the implant (Fig. 1).

Except for schooling, baseline characteristics were similar between groups (Table 1).

3.1. Bleeding patterns in the first year after delivery

In the ITT analysis, we included all randomized postpartum women (n=100). In the PP analysis, we analyzed 98 participants in RP 1 (early group: 48, delayed group: 50), 86 in RP 2 (early group: 42, delayed group: 44) and 85 in RPs 3 and 4 (early group: 44, delayed group: 41). There were two participants who did not complete the diary in the RP 2 but completed it in RPs 3 and 4.

Bleeding patterns were similar between groups over 12 months of follow-up regardless of analysis type (i.e., ITT and PP). Amenorrhea was the most common bleeding pattern in both groups during all RPs. In the ITT analysis, amenorrhea rates ranged from 52% to 56% in the early group and from 46% to 62% in the delayed group (Fig. 2). In the PP analysis, amenorrhea rates ranged from 58.3% to 61.9% in the early group and from 56.1% to 63.6% in the delayed insertion group (online Fig. 1 supplementary). Prolonged bleeding episodes ranged from 0% to 2% in both groups and analyses (Fig. 2 and online Fig. 1 supplementary).

Table 1
Baseline demographic and clinical characteristics of postpartum women randomized to early and delayed etonogestrel implant insertion

	Early insertion (n=50)	Delayed insertion (n=50)	p
	Mean (SD)		
Age (years)	26.9 (5.4)	25.7 (4.9)	.23[a]
Family income (US $, monthly)	518.9 (257.6)	583.7 (446.2)	.41[a]
BMI (kg/m^2)	29.4 (4.6)	30.2 (5.6)	.29[a]
	***N* (%)**		
Parity			.87[b]
1	14 (28)	16 (32)	
2	20 (40)	19 (38)	
≥3	16 (32)	15 (30)	
Current delivery			1[b]
Vaginal	36 (72)	36 (72)	
Cesarean section	14 (28)	14 (28)	
Educational level (years)			.02[b]
5–7	15 (30)	6 (12)	
≥8	35 (70)	44 (88)	
Smoking			.75[b]
Yes	6 (12)	5 (10)	
No	44 (88)	45 (90)	
Newborn sex			.23[b]
Male	28 (56)	22(44)	
Female	22 (44)	28 (56)	

Early insertion: postpartum women whose etonogestrel implants were inserted within the first 48 h after delivery; delayed insertion: postpartum women whose etonogestrel implants were inserted at 6 weeks of delivery.
n: number of women; N: absolute number; SD: standard deviation.
[a] t test, data reported in mean and standard deviation.
[b] χ^2 test.

Amenorrhea rates were similar between exclusively breastfeeding women and nonexclusively breastfeeding ones (online Table 1 supplementary).

3.2. BMI changes in the first year after delivery

At the 360-day visit, BMI decreased 10.3% and 11% in the early group and delayed insertion group, respectively, compared to baseline, without difference between groups (Table 2).

Ten women (10% of all participants) gained weight during the study period (4 in the delayed and 6 in the early insertion group), but none requested implant removal for this reason.

3.3. Implant continuation and satisfaction rates

At 12 months postpartum, the ENG implant continuation rates were similar between the groups, 98% (49/50) and 100% (50/50) in the early and delayed insertion group, respectively (p=.99). More than 90% of postpartum women were satisfied or very satisfied with the ENG implant at the 360-day visit regardless of the timing of insertion (p=.90). The agreement between the Likert and face scales was 92%.

4. Discussion

We showed that the timing of postpartum ENG implant insertion does not affect bleeding patterns, BMI changes, and method satisfaction and continuation rates during 12 months of follow-up. Amenorrhea was the most common bleeding pattern over 12 months in both groups. Implant continuation rates were near 100% in both groups. More than 90% of women were satisfied or very satisfied with the ENG implant.

Two randomized controlled trials have evaluated bleeding patterns associated with ENG implant use in the postpartum period [8,11,24]. Compared to our study, both studies have smaller sample sizes and higher loss to follow-up rate (20%–33%) [8,24]. They do not describe the bleeding data collection process in detail and do not describe bleeding patterns according to WHO's terminology for progestogen-only contraceptives [8,21,24]. One of these studies reported amenorrhea as the most common bleeding pattern at 6 months after delivery but did not present amenorrhea rates according to timing of ENG implant insertion [8].

It is not surprising that we found BMI decreases in ENG implant users in the postpartum period, as have previously been reported [25–28]. Previous studies, however, have not compared the effect of the timing of postpartum implant insertion on BMI changes.

The main reasons for discontinuation of the ENG implant inserted postpartum are unfavorable bleeding patterns and weight gain [3,13]. Outside the postpartum period, frequent and prolonged bleedings are the patterns most associated with implant discontinuation [14]. Since prolonged bleeding was unusual (0%–2%) in our study, we did not have any discontinuation for this reason. Weight gain did not lead to discontinuation in our study, even though 10% of the participants gained weight after delivery. Postpartum weight loss depends on many factors, including pre-pregnancy BMI, which we did not evaluate [29,30].

Timing of implant insertion seems not to impact continuation rates [4,5,8,11,13,24], which is consistent with our findings. Our continuation rates were higher than those previously reported in studies that followed women for 12 months postpartum [3–5,13, 24,31]. We attribute our high continuation rates to the anticipatory guidance about the ENG implant.

In the absence of barriers to removal, high LARC continuation rates generally reflect high satisfaction rates [32]. We found high satisfaction rates with the ENG implant in both groups. A previous study also showed high satisfaction rates with postpartum ENG implant in adolescents, regardless of the timing of insertion [24].

Strengths of our study compared to other postpartum ENG studies included the high implant continuation rates, bleeding patterns reported according to WHO's terminology and the use of two scales to measure method satisfaction. Face scale can be used to access overall satisfaction with a given treatment [33, 34], especially for patients with low literacy skills. In Brazil, the rate of functional illiteracy is 23% [35], which can impact participants' ability to understand the Likert scale. For this reason, we measured the agreement of Likert scale with another scale not affected by functional illiteracy (i.e., face scale).

Our study also has limitations. First, it was a secondary analysis of a randomized trial for which the primary outcome was infant growth [7]. Emphasis on infant growth and easy access to delayed placement may have influenced our results. Also, our sample size may be underpowered for analyzing multiple outcomes, especially continuation rates. However, a post hoc estimate of effect size for our outcomes indicated a low probability of demonstrating clinically meaningful results (data not shown). Nevertheless, our results should be confirmed with studies designed to evaluate the outcomes presented here. Second, we increased the chance of having a type 2 error because we adjusted the p value for multiplicity to avoid a type 1 error as a conservative approach. Third, to improve participant adherence to the study protocol during the postpartum period, we developed a novel and simplified diary to collect bleeding data. Our findings should be confirmed with studies using conventional bleeding diaries. Finally, the duration of normal postpartum lochia can vary among women [36], which could have led to inaccurate reporting.

In conclusion, our study provides preliminary data suggesting that women who underwent immediate postpartum insertion of the ENG implant did not have different bleeding patterns, BMI changes, and 12-month satisfaction and continuation rates

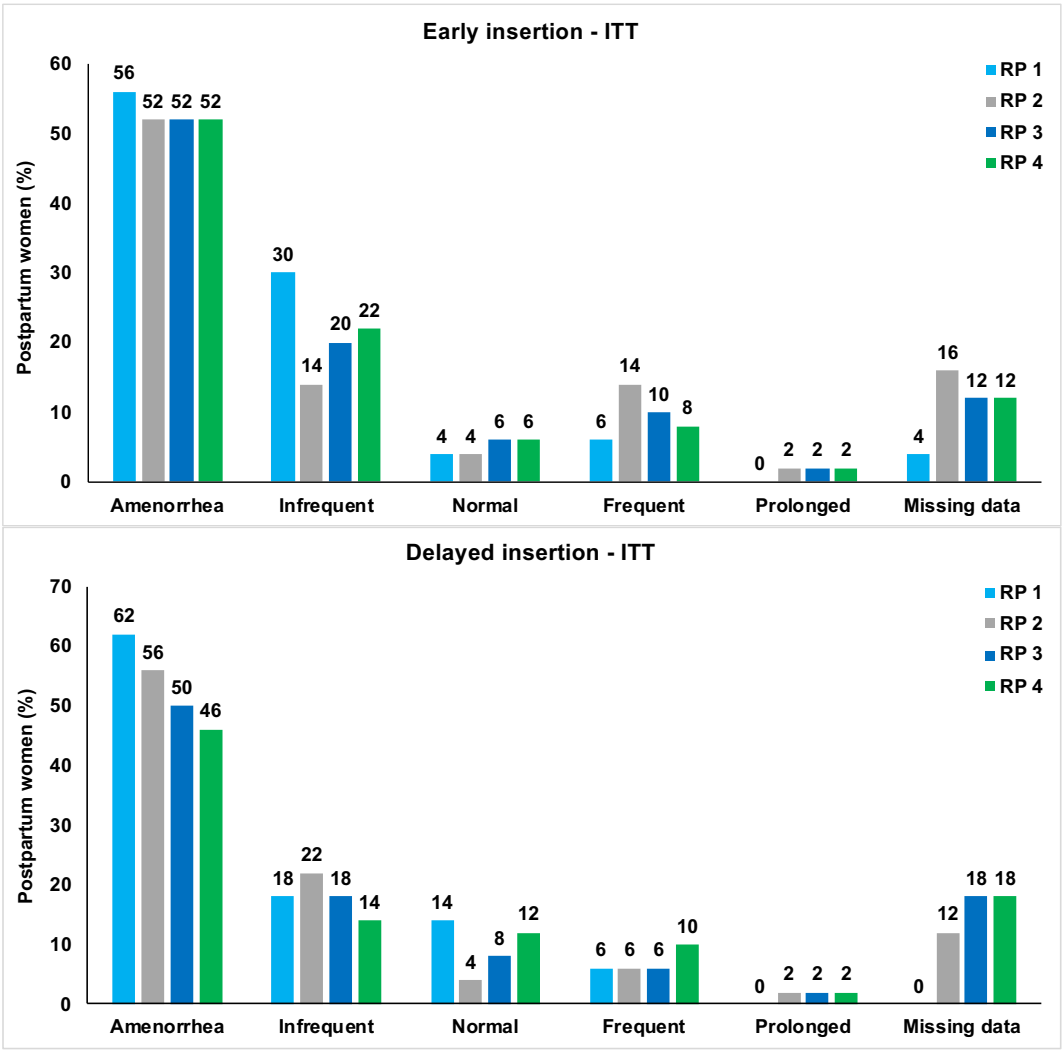

Fig. 2. Timing of etonogestrel-releasing implant insertion and bleeding patterns of postpartum women over the first year since delivery (ITT analysis). ITT = missing data included. First day of RP1 was up to PPD 2 for both groups. RP1: from 0 to 90 days after randomization; RP2: from 91 to 180 days after randomization; RP3: from 181 to 270 days after randomization; RP 4: from 271 to 360 days after randomization. Bleeding patterns were similar between the groups using χ^2 test. Early insertion: etonogestrel implant inserted within 48 h of delivery. Delayed insertion: etonogestrel implant inserted at 6 weeks postpartum.

compared to those who underwent delayed insertion. Our results may help clinicians provide anticipatory guidance to women considering immediate postpartum ENG implant insertion.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.contraception.2019.05.007.

Table 2
Timing of etonogestrel implant insertion and postpartum women's BMI over the first year of the delivery

Time (days)	Early insertion Mean (SD), kg/m^2	Delayed insertion Mean (SD), kg/m^2	p** (between groups)
Baseline	29.1 (4.6)*	30.0 (5.7)#	.34
90	26.5 (4.1)	27.2 (5.5)	.49
180	26.5 (4.9)	27.0 (5.9)	.66
360	26.4 (5.0)*	26.7 (6.2)#	.72

Early insertion: postpartum women whose etonogestrel implants were inserted within the first 48 h after delivery; delayed insertion: postpartum women whose etonogestrel implants were inserted at 6 weeks of delivery.
*, #: same symbols represent p<.0001 in the intragroup comparison using mixed-effects linear regression model.
Baseline: randomization day (up to postpartum day 2 for both groups).
** p = comparison between groups using a mixed-effect linear regression model.

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Disclosures

Dr. Braga has given ad hoc invited lectures for Merck. Dr. Nadai has given ad hoc invited lectures for Merck and Bayer. Drs. Ferriani and Vieira have served on Medical Advisory Boards and given ad hoc invited lectures for Merck and Bayer. The other authors did not report any potential conflicts of interest.

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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