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The Lactational Effects of Contraceptive Hormones: an Evaluation (LECHE) Study

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ABSTRACT

Objective: To estimate the proportion of women for whom use of hormonal contraception was associated with reporting a decreased breast milk supply.
Study design: The Lactational Effects of Contraceptive Hormones: an Evaluation ("LECHE") Study was an anonymous, internet-based, exploratory, cross-sectional survey of postpartum women using approximately 70 questions. Women were eligible to participate in the survey if they were 18 years or older, had a singleton infant between 3 and 9 months of age, had breastfed this infant for any amount of time and could read English. The survey included questions about breastfeeding, reproductive health, demographic characteristics and the timing of postpartum events.
Results: A total of 3971 participants clicked on the survey. Our final study population included 2922 participants. Overall, 1201 (41%) reported having had milk supply concerns at some point in the first 12 weeks postpartum. The median time from birth until milk supply concerns was 3 weeks (IQR 1–7). Eight hundred fifty-two women (29%) started hormonal contraception in the first 12 weeks postpartum. Fifteen percent (127/852) of women reported new or additional milk supply concerns after starting hormonal contraception. Reported milk supply concerns were higher for women who used hormonal contraception than those who did not (44% vs. 40%; p=.05) Adjusted hazard ratios (HRs) assessing the association between contraceptive use and time to milk supply concerns were not statistically significant (HR 1.18, 95% confidence interval 0.94–1.47 for any type of hormonal contraception).
Conclusions: This study found a slightly increased proportion of reported milk supply concerns among women who started hormonal contraception.
Implications: It is important for caregivers in the postpartum period to recognize the potential for multiple factors, including initiation of hormonal contraception, to affect breastfeeding. Patient-centered counseling can help elicit women's values and preferences regarding breastfeeding and pregnancy prevention.

1. Introduction

Optimizing the health and well-being of both mothers and infants guides counseling and care in the postpartum period. Breastfeeding and birth spacing are two public health priorities that directly influence the health of mother and child. Breastfeeding confers multiple benefits for infants and mothers [1]. Similarly, pregnancy intervals of at least 18–24 months are associated with improved infant and maternal health. Adequate birth spacing is also associated with decreased risk of low birth weight, preterm birth and other comorbidities [2–5]. Efforts to encourage contraception in the postpartum period aim to help women optimally space their births and avoid unintended or mistimed pregnancies [6,7].

It is biologically plausible that exogenous progestins and estrogens from hormonal contraceptives may affect breast milk synthesis. High levels of maternal progesterone suppress breast milk production during pregnancy. After delivery of the placenta, maternal progesterone levels fall, and breast milk production can proceed [11,12]. High levels of estrogen during pregnancy also contribute to suppression of lactation.

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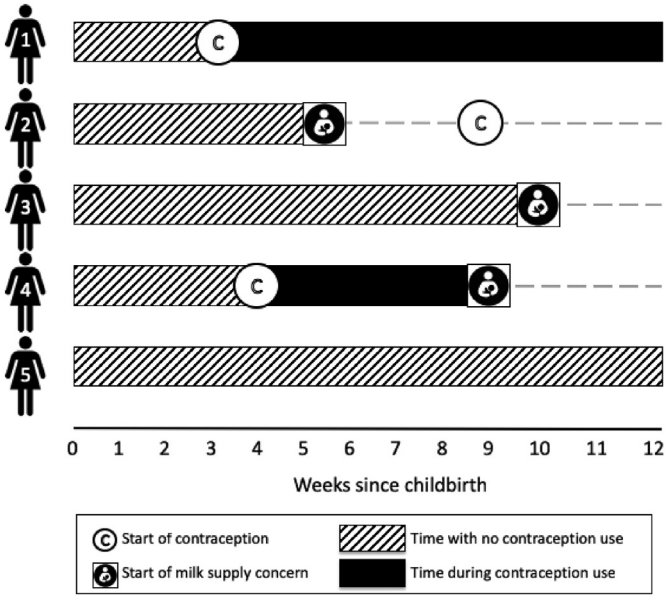

Fig. 1. Exposure and outcome times and influence on person-time at risk. This figure illustrates several temporal patterns of exposure and outcome that could occur. A milk supply concern may occur before hormonal contraception use begins (person 2), in cases where there is not hormonal contraception use (person 3), after hormonal contraception use (person 4) or not at all (person 1 and person 4). For hormonal contraception use to be a potential cause of milk supply concerns, it must occur before the outcome. In an analysis that does not allow for a time-varying exposure, persons 1, 2 and 4 would all be considered part of the exposed group; however, person 2 is not at risk for the outcome after the exposure has occurred. A woman is censored at the time of reported milk supply concern and thus no longer contributes person-time at risk (dashed lines). The extended time-dependent Cox model enables comparison of the person-time at risk during which contraception use occurs (black bars) compared with person-time at risk in which contraception use has not occurred (dashed bars).

[13] Breastfeeding women frequently use hormonal contraceptives. The potential impact of hormonal contraceptives on breast milk synthesis has prompted examination of their effect on lactation, which could ultimately impact infant growth and development [8–10].

Studies have sought to quantify hormonal contraceptive impact on breast milk supply and infant growth [8–10,14–17]. Overall, these studies have not found an adverse effect of hormonal contraceptives on breast milk supply; however, the studies generally had small sample sizes, used heterogeneous contraceptive methods and were limited to healthy women with term infants. Absent conclusive evidence, contraceptive management recommendations differ between family planning and lactation experts. Counseling by lactation experts may focus on the data limitations, case reports [14] or anecdotal evidence suggesting milk suppression in order to protect breastfeeding [18]. In contrast, family planning experts may emphasize the evidence that shows no impact of hormonal contraception on breastfeeding [19].

This study elicited women's breastfeeding experiences following introduction of contraceptive hormones. Our objective was to estimate the proportion of women in whom use of hormonal contraception was associated with reporting decreased breast milk supply.

2. Materials and methods

2.1. Study population and survey development

The Lactational Effects of Contraceptive Hormones: an Evaluation ("LECHE") Study was an anonymous, internet-based, exploratory, cross-sectional survey of postpartum women using Qualtrics software (Provo, UT, USA). Respondents could take the survey only once from the same IP address. Women were eligible to participate in the survey if they were 18 years or older, had a singleton infant between 3 and 9 months of age, had breastfed this infant for any amount of time and could read English. The survey was distributed via social media, listservs and networks of new mothers and breastfeeding groups. The survey title used only the LECHE acronym with no explicit mention of contraception to avoid biasing responses. The Biomedical Institutional Review Board of the University of North Carolina at Chapel Hill gave ethical approval for the study. Participation constituted consent. We used STROBE and CHERRIES guidelines for reporting the results of this cross-sectional internet-based study. [20,21].

The survey included questions about breastfeeding, reproductive health and demographic characteristics. Respondents were asked to recall the timing of postpartum events and report the week at which these

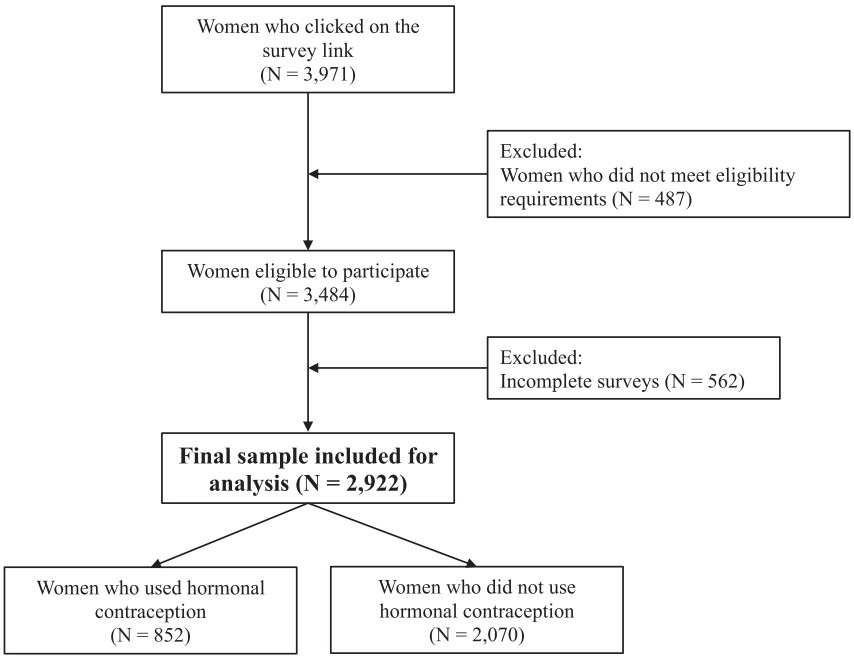

Fig. 2. Flowchart of study population and survey exclusions.

events occurred, if at all, in the first 12 weeks postpartum: resuming intercourse, starting contraception, infant sleeping through the night, returning to work, supplemental feeding and breastfeeding cessation. Later in the survey, we asked directly about timing of contraception use and milk supply concerns, including changes in milk supply, use of medications or supplements to increase milk supply and stopping hormonal contraception due to decreased milk supply. We used standard questions from the Infant Feeding Practices Survey where appropriate [22].

2.2. Primary exposure

Our primary exposure was hormonal contraceptive use in the first 12 weeks postpartum. We defined this as use of any contraceptive containing hormones, including oral contraceptive pills; hormonal intrauterine devices; contraceptive injections; and contraceptive implants, patches and rings. We analyzed a combined exposure variable that indicated use of any hormonal contraceptive(s) and also created exposure variables for each contraceptive method separately.

2.3. Primary outcome

We created a composite variable to represent our primary outcome of milk supply concerns. Women were asked, "Thinking back to the first 12 weeks of your baby's life, did you experience or do any of the following?" and could check all responses that applied. Respondents were considered to have milk supply concerns if they reported any of the following responses: (1) had a sharp decrease in my breast milk supply; (2) had a gradual decrease in my breast milk supply; (3) started taking prescription medications to increase milk production or (4) started using galactagogues (teas, foods, herbal supplements) to increase milk production. We also included women who reported stopping hormonal contraception due to milk concerns as part of our composite outcome.

2.4. Statistical analysis

We calculated proportions of women who reported various demographic and reproductive health characteristics, including reported concerns about milk supply, reasons for stopping breastfeeding and reported effect of hormonal contraception on breast milk supply. Our bivariate analyses evaluated factors associated with milk supply concerns. We also calculated the proportion of women with milk supply concerns among those using hormonal contraception. We used Pearson's chi-square to test differences between categorical variables, using Fisher's Exact Test when indicated.

We evaluated temporality of events based on responses about the week an event occurred. To maximize the utility of these temporal data, we conducted a time-to-event analysis with our composite milk supply concern variable as the outcome. (Fig. 1) Contraceptive use for each woman does not remain constant from our time of origin (time of birth) to the end of follow-up (12 weeks postpartum), and milk supply concerns may occur prior to starting contraception. Therefore, we used an extended Cox proportional hazards model in which we treated hormonal contraception use as a time-dependent (varying) exposure [23] to estimate hazard ratios (HRs) for hormonal contraception use on milk production or supply concerns. This model enables comparison of the person-time during which women are at risk for milk supply concerns after hormonal contraception use with the person-time at risk in which hormonal contraceptive use has not occurred. Based on our bivariate analyses and known factors from the literature that may influence contraception use and milk supply, we adjusted for age, race, parity, overweight or obesity prior to pregnancy, mode of delivery and whether the infant was in the neonatal intensive care unit [24–26].

We repeated these analyses for each method of contraception separately, including both hormonal and non-hormonal types of contraception for comparison. We performed all statistical analyses using SAS 9.3 (Cary, NC, USA).

3. Results

From January 28 to May 27, 2016, the LECHE survey was available for completion on Facebook, listservs and other social media platforms. A total of 3971 participants clicked on the survey and completed it at least partially (Fig. 2). Our final study population included 2922 women. Most respondents were white (87%) and had a college degree or higher education (75%). About half (54%) were primiparous. Almost all women reported that they intended to feed their infants breast milk exclusively (98%). (Table 1) The average time women intended to feed their infants breast milk was 14 months.

In the first 12 weeks postpartum, 1201 (41%) women experienced milk supply concerns. Eight hundred fifty-two women (29%) started hormonal contraception in the first 12 weeks postpartum. The most commonly used hormonal contraceptive was the progestin-only oral contraceptive (50% of hormonal contraceptive users) (Table 2).

Of the 852 women who started hormonal contraception, 67% (572/852) had no milk supply concerns prior to starting, and 84% (478/572)

Table 1
Baseline characteristics of women in the LECHE sample, grouped by milk supply concerns[a]

Characteristic[b]	Without Milk Supply Concerns (N=1721)	With Milk Supply Concerns (N=1201)	p value
	No. (%)	No. (%)	
Age (years)			
18–24	127 (7.4)	80 (6.7)	.13
25–29	486 (28.2)	377 (31.4)	
30–34	760 (44.2)	481 (40.1)	
35–39	303 (17.6)	225 (18.7)	
≥40	44 (2.6)	38 (3.2)	
Parity			
1	811 (47.1)	756 (63.0)	<.01
2+	903 (52.5)	437 (36.4)	
Race/ethnicity			
White	1547 (89.9)	1008 (83.9)	
African-American	21 (1.2)	26 (2.2)	<.01
Hispanic/Latino	92 (5.4)	94 (7.8)	
Other	58 (3.4)	71 (5.9)	
Educational status			
High school or less	73 (4.2)	37 (3.1)	
Some college	382 (22.2)	250 (20.8)	.15
College graduate or higher	1265 (73.5)	914 (76.1)	
Marital status			
Married/living with partner	1680 (97.6)	1167 (97.2)	
Single	29 (1.7)	21 (1.8)	.42
Divorced/separated/widowed	11 (0.6)	13 (1.1)	
Yearly household income			
Less than $50,000	398 (23.1)	302 (25.2)	
$50,000–$125,000	833 (48.4)	551 (46.0)	.31
Over $125,000	471 (27.4)	339 (28.2)	
Health insurance			
Private	1195 (69.4)	849 (70.7)	
Government (Medicaid)	345 (20.1)	242 (20.2)	.42
Tricare	105 (6.1)	73 (6.1)	
Self-pay	65 (3.8)	32 (2.7)	
Ever overweight/obese	475 (27.6)	400 (33.3)	<.01
Preterm birth this pregnancy	87 (5.1)	79 (6.6)	.08
Vaginal delivery	1305 (75.8)	804 (66.9)	<.01
Baby spent time in NICU	137 (8.0)	129 (10.7)	.01
Breastfeeding Intentions			
Breast milk only	1686 (98.0)	1163 (96.8)	.07
Breast milk and formula	34 (2.0)	36 (3.0)	

[a] Milk supply concerns are defined as reporting a sharp or gradual drop in milk supply, use of prescription medications to increase milk supply, use of over-the-counter galactagogues (teas, foods, herbal supplements) or stopping their contraception method due to a reduction in milk supply.

[b] Missing values are as follows: age (1), parity (15), race/ethnicity (5), educational status (1), marital status (1), yearly household income (28), health insurance (16), breastfeeding intentions (3), mode of delivery (8) and NICU (11).

Table 2
Feeding-related events and contraceptive use in the postpartum period for women in the LECHE sample, grouped by milk supply concerns[a]

	Without milk supply concerns (*n*=1721)	With milk supply concerns (*n*=1201)	p value
	No. (%)	No. (%)	
Events in the first 12 weeks postpartum			
Stopped breastfeeding	44 (2.6)	118 (9.8)	<.01
Sought professional breastfeeding help	759 (44.1)	806 (67.2)	<.01
Used a nipple shield	348 (20.2)	394 (32.8)	<.01
Used nonprescription galactagogues[b]	–	1052 (88.6)	–
Started pumping	1219 (70.8)	1044 (86.9)	<.01
Introduced formula	152 (8.8)	388 (32.3)	<.01
Was separated from baby for >48 h	26 (1.5)	49 (4.1)	<.01
Returned to work (full or part time)	469 (27.3)	425 (35.4)	<.01
Resumed intercourse	1011 (58.7)	688 (57.3)	.43
Discussed the following with care provider			
Birth control/family planning	1546 (92.6)	1063 (92.1)	.61
Breastfeeding	1531 (89.0)	1071 (89.2)	.89
Effects of birth control on breastfeeding	610 (35.4)	435 (36.2)	.73
Effects of breastfeeding on fertility	805 (46.8)	553 (46.0)	.69
Any HC use	478 (27.7)	374 (31.1)	.05
HC use before 6 weeks postpartum	60 (3.5)	36 (3.0)	.20
Time of HC start, mean wk (SD)	7.2 (2.6)	7.6 (2.7)	.05
Type of HC use[c]			
Progestin-only pill	229 (13.3)	199 (16.6)	.01
Combined HC pills	32 (1.9)	40 (3.3)	.01
Contraceptive implant	33 (1.9)	11 (0.9)	.03
Levonorgestrel intrauterine device	172 (10.0)	113 (9.4)	.60
Depot medroxyprogesterone injection	24 (1.4)	24 (2.0)	.21
Contraceptive patch or ring	7 (0.4)	13 (1.1)	.03
Type of non-HC use[c]			
Vasectomy	63 (3.6)	35 (3.0)	.31
Female sterilization	46 (2.7)	24 (2.0)	.27
Copper intrauterine device	63 (3.6)	46 (3.8)	.81
Lactational amenorrhea	360 (20.9)	240 (20.0)	.54
Fertility awareness methods	185 (10.7)	109 (9.1)	.14
Condoms	598 (34.7)	466 (38.9)	.03
Withdrawal	407 (23.7)	254 (21.2)	.11
Perceived effect of hormonal birth control on milk supply among women initiating hormonal birth control (n=852; 478 without MSC, 374 with MSC)			
Increased milk production	1 (0.2)	1 (0.3)	<.01
Didn't affect milk production	340 (71.1)	197 (52.7)	
Reduced milk production	29 (6.1)	60 (16.0)	
Do not know	108 (22.6)	116 (31.0)	

HC, hormonal contraception; MSC, milk supply concerns.
[a] Milk supply concerns are defined as reporting a sharp or gradual drop in milk supply, use of prescription medications to increase milk supply, use of over-the-counter galactagogues (teas, foods, herbal supplements) or stopping their contraception method due to a reduction in milk supply.
[b] Galactagogues include teas, foods or herbal supplements.
[c] Women could report use of more than one type of contraception.

did not report any new milk concerns after starting. Fifteen percent (127/852) of women reported new or additional milk supply concerns after starting hormonal contraception. Women who used hormonal contraception reported more milk supply concerns than those who did not (44% vs. 40%; p=.05). Of the 259 women who had milk supply concerns prior to starting hormonal contraception, 13% (33/259) reported additional milk supply concerns after starting hormonal contraception. Of the women who had no milk supply concerns prior to starting hormonal contraception, 16% (94/572) reported milk supply concerns after initiating contraception.(Fig. 3).

The majority of women (63%) who started hormonal contraception reported that it did not affect their milk production; however, this perception differed among women who reported milk supply concerns (53%) vs. those who did not report milk supply concerns (71%). The remaining 37% reported perceiving an increase or reduction in breast milk production or reported that they did not know. Sixteen percent of women with milk supply concerns who started hormonal contraception reported that it reduced their milk production. Six percent of women without milk supply concerns reported a reduction in milk production. More women with milk supply concerns reported that they did not know whether there was an effect of hormonal contraception on their breast milk supply (31% vs. 23%, p<.01) (Table 2).

In the whole cohort, median time to milk supply concern was 3.0 weeks (IQR 1.0–7.0 weeks). Median times postpartum to milk supply concerns were 3.0 (IQR 1.0–5.0) weeks for women who reported milk supply concerns prior to initiation of hormonal contraception, 9.0 (IQR 8.0–11.0) weeks for women who reported milk supply concerns after initiation of hormonal contraception and 3.0 (1.0–6.0) weeks for women who never used hormonal contraception.

The adjusted HRs assessing the association between contraceptive use and time to milk supply concerns were not significant either for hormonal contraceptive use overall [HR 1.18, 95% confidence interval (CI) 0.94–1.47] or for specific types of contraception (Table 3).

4. Discussion

This exploratory, cross-sectional study using a large convenience sample of breastfeeding women suggests that women who use hormonal contraception experience slightly increased milk supply concerns after starting hormonal contraception. When we examined confounding factors that can affect milk supply, such as going back to work, obesity, age and separation from the baby, and accounted for the temporal order of starting hormonal contraception before experiencing milk supply concerns, the incidence of milk supply concerns was similar between women who initiated hormonal contraception and women who did not (HR 1.18, 95% CI 0.94–1.47 for any type of hormonal contraception). This study adds to the existing literature by exploring reported impact of hormonal contraception on breastfeeding among a population of recent or currently breastfeeding mothers. The proportion of women who reported issues is important

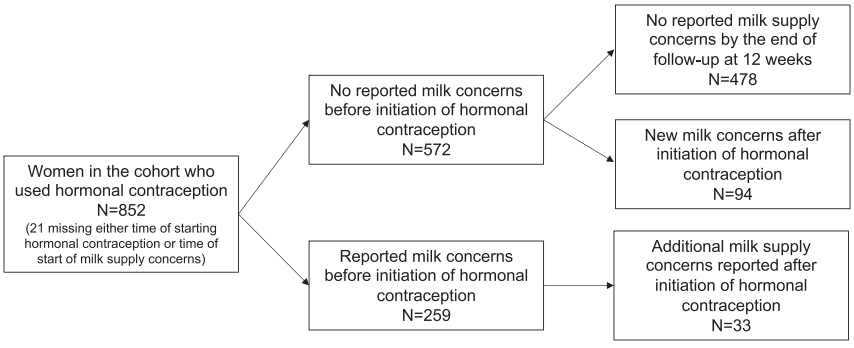

Fig. 3. Milk supply concerns among women who started hormonal contraception before and after initiation of hormonal contraception.

Table 3
Cox regression of the association between contraception use and milk supply concerns, with contraception initiation as a time-varying exposure[a]

Contraception use	Total	Milk supply concerns		
		No. with milk concerns	Unadjusted HR (95% CI)	Adjusted[b] HR (95% CI)
Any hormonal contraception				
No	2070	827	1.00	1.00
Yes	852	374	1.21 (0.97–1.52)	1.18 (0.94–1.47)
Progestin-only pills				
No	2494	1002	1.00	1.00
Yes	428	199	1.38 (1.06–1.81)	1.31 (1.00–1.72)
Combined oral contraceptive pills				
No	2850	1161	1.00	1.00
Yes	72	40	1.23 (0.58–2.59)	1.18 (0.56–2.49)
Levonorgestrel IUD				
No	2637	1088	1.00	1.00
Yes	285	113	0.98 (0.65–1.49)	0.98 (0.65–1.49)
Copper IUD				
No	2813	1155	1.00	1.00
Yes	109	46	1.03 (0.51–2.07)	1.01 (0.50–2.03)
Lactational amenorrhea method				
No	2322	961	1.00	1.00
Yes	600	240	1.06 (0.86–1.31)	1.11 (0.89–1.37)
Condoms				
No	1858	735	1.00	1.00
Yes	1064	466	1.06 (0.84–1.34)	1.09 (0.86–1.37)

IUD, intrauterine device.
[a] Time of milk supply concerns was defined as reported starting week of experiencing a sharp or gradual drop in milk supply, beginning use of prescription medication to increase milk supply, beginning use of galactagogues, or set at the midpoint between contraception start and 12 weeks for respondents indicating stopping hormonal contraception due to reduced milk supply.
[b] Adjusted for maternal age, race/ethnicity, parity, ever overweight, baby in NICU and mode of delivery.

to consider, as perceptions of milk supply may influence infant feeding practices even if milk supply actually remains consistent [30–32].

This study highlights the complexity of determining the extent to which contraceptive hormones may affect reported breast milk supply. Some women experienced a decrease in milk supply and discontinued their hormonal contraception, yet other factors occurring at the same time, such as returning to work and pumping, may also play a role in discontinuing breastfeeding.

The strengths of this study include the large sample size of breastfeeding women, which allows for detection of potentially small effects of hormonal contraception on milk supply concerns. We used questions from previous infant feeding studies to assess milk supply concerns and questions based on known risk factors for milk supply reduction. We also used a novel survey approach of having women report the order of events in the postpartum period; this approach allowed us to evaluate milk supply concerns in the context of other postpartum events. We were also able to adjust for a number of factors that may affect perception of breast milk production.

This study had multiple limitations. First, the population sampled did not represent a cross-section of women in the United States who initiate breastfeeding. Nearly all of the women in this study (98%) expressed the intention to feed their baby only breast milk, which may indicate a strong motivation to breastfeed. These women may have avoided contraceptive hormones or have been able to persist and sustain breastfeeding in the setting of milk supply concerns more than women less motivated to breastfeed. We could only ascertain perception of milk supply concerns, and we assumed that women using galactagogues experienced decreased milk supply. Our study sample was older, more educated and less racially diverse than the average postpartum population in the United States [33]. All of these factors may limit the generalizability of this study. Selection bias and recall bias are also possible, as women were asked to recall events in a notoriously tiring period of life [34]. Limitations inherent to internet-based studies are also possible, such as inability to verify participants' gender, age of infant or breastfeeding status. We tried to limit duplicate respondents by only allowing the survey to be taken once from a unique IP address.

This study was not able to capture the experience of many women who struggle with breastfeeding. Approximately 81% of women who gave birth in the United States in 2016 initiated breastfeeding. By 3 months postpartum, only 44% of women in the United States were still exclusively breastfeeding [35]. Therefore, this sample was likely not representative of what many women who breastfeed experience as barriers to initiating or continuing to breastfeed.

Caregivers in the postpartum period should recognize the potential for multiple factors, including initiation of hormonal contraception, to affect women's experiences of their breast milk production. While the risk of hormonal contraception having an impact on breast milk production may be small, for some women, any risk may be unacceptable. Women with milk supply concerns prior to initiating hormonal birth control may be more likely to discontinue their method, thus exposing them to risk for unplanned pregnancy. Women who experience milk supply concerns may therefore benefit from follow-up to ensure that they are utilizing an effective contraceptive method. For other women, any risk of an unintended pregnancy may be unacceptable and a small risk of a drop in milk supply completely acceptable.

Studying women who might be more vulnerable to breastfeeding difficulties could assess whether the association between breastfeeding and hormonal contraceptives is more pronounced when more barriers are present. In the meantime, patient-centered counseling may allow providers to elicit women's values and preferences regarding breastfeeding and pregnancy prevention and engage in shared decision making about contraception.

Conflicts of interest

None of the authors has conflicts of interest to declare.

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