Delayed onset of lactogenesis among first-time mothers is related to maternal obesity and factors associated with ineffective breastfeeding[1–4]

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ABSTRACT

Background: Delayed onset of lactogenesis (OL) is most common in primiparas and increases the risk of excess neonatal weight loss, formula supplementation, and early weaning.

Objective: We examined variables associated with delayed OL among first-time mothers who delivered at term and initiated breastfeeding ($n = 431$).

Design: We conducted in-person interviews during pregnancy and at days 0, 3, and 7 postpartum and extracted obstetric and newborn information from medical records. We defined OL as delayed if it occurred after 72 h and used chi-square analysis to examine its association with potential risk factors across 6 dimensions: *1*) prenatal characteristics, *2*) maternal anthropometric characteristics, *3*) labor and delivery experience, *4*) newborn characteristics, *5*) maternal postpartum factors, and *6*) infant feeding variables. We examined independent associations by using multivariable logistic regression analysis.

Results: Median OL was 68.9 h postpartum; 44% of mothers experienced delayed OL. We observed significant bivariate associations between delayed OL and variables in all 6 dimensions ($P < 0.05$). In a multivariate model adjusted for prenatal feeding intentions, independent risk factors for delayed OL were maternal age $\geq$30 y, body mass index in the overweight or obese range, birth weight >3600 g, absence of nipple discomfort between 0–3 d postpartum, and infant failing to "breastfeed well" $\geq$2 times in the first 24 h. Postpartum edema was significant in an alternate model excluding body mass index ($P < 0.05$).

Conclusions: The risk factors for delayed OL are multidimensional. Public health and obstetric and maternity care interventions are needed to address what has become an alarmingly common problem among primiparas. *Am J Clin Nutr* 2010;92:574–84.

INTRODUCTION

Stage I lactogenesis, or secretory initiation, occurs during pregnancy and is defined by the differentiation of mammary alveolar epithelial cells into specialized secretory cells, termed *lactocytes* (1). At this stage, the mammary gland is capable of producing small quantities of immunoglobulin-rich mammary secretion, known as colostrum. Stage II lactogenesis, or secretory activation, is defined as the initiation of copious milk secretion. Lactose is the predominant milk osmolyte; thus, it is a sudden increase in intracellular lactose that draws water into the lactocyte and accounts for the new mother's noticeable increase in milk volume that is the hallmark of stage II lactogenesis. In humans, this process is triggered by the withdrawal of progesterone after delivery of the placenta (2).

Maternal perception of the milk "coming in" is strongly correlated with biochemical and milk transfer indicators of stage II lactogenesis (3–5). The perception of onset of stage II lactogenesis beyond 72 h postpartum is considered delayed onset of lactogenesis (delayed OL) (5–8). We previously reported the relative risk (RR) of excess neonatal weight loss to be 7 times greater among exclusively breastfed infants of mothers with perceived delayed OL than in those with timely OL (timely OL; 40.4% compared with 5.7%, $P < 0.0001$) (5).

On a longer-term basis, women experiencing delayed OL are at greater risk of short breastfeeding duration (9–11). For example, we recently reported that among a sample of low-income California women who initiated breastfeeding ($n = 128$), the odds of any breastfeeding at 6 wk postpartum were nearly 5-fold higher in women with timely OL than in those with delayed OL (11). It is critical to identify risk factors for delayed OL, so that women with these risk factors are followed more closely postpartum to provide appropriate breastfeeding support until lactation is fully established.

Several risk factors are associated with delayed OL, with the strongest known association being primiparity (4–7, 12, 13). In a previous study, we reported the prevalence of delayed OL to be 33% among primiparas and 5% among multiparas (5). Other factors cited include cesarean delivery (5–7, 12–14), longer duration of labor (4–6), and elevated cortisol concentrations in both the mother (4, 7) and the fetus (4). Several studies have reported an association between elevated maternal body mass index (BMI; in kg/m^2) (5, 8, 11) or "heavy body build" (6) and

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delayed OL. However, for one of these studies, the relation between BMI and delayed lactogenesis was no longer significant when parity was included in the model (8). An additional report did not find an association between maternal obesity and prevalence of delayed OL (13).

Given that the risk of delayed OL is several-fold higher in first-time mothers, we sought to examine the factors associated with delayed OL specifically in primiparas as part of a longitudinal cohort study examining barriers to early lactation success in a multiethnic population of first-time mothers (15).

SUBJECT AND METHODS

Screening and enrollment

We recruited women receiving prenatal care through the University of California Davis Medical Center (UCDMC) for this longitudinal cohort study. We restricted the study to first-time mothers, because they are the most likely to experience difficulties in establishing breastfeeding (5). We further targeted mothers expecting a term delivery of a healthy infant and living within the vicinity of the UCDMC. The latter served the dual purposes of increasing home-visit feasibility and increasing the socioeconomic diversity of the cohort. Thus, inclusion criteria were as follows: participants between 32–40 wk gestation at time of interview expecting their first live-born infant, carrying a single fetus, speaking either English or Spanish, and living within the catchment area (8-mile radius of the UCDMC in Sacramento, CA). Exclusion criteria were as follows: mothers who were referred to the UCDMC due to medical condition, those with a known absolute contraindication to breastfeeding, or those who were aged <19-y-old and not able to obtain parental consent. All women receiving prenatal care through the UCDMC between January 2006 and December 2007 were screened for eligibility. The University of California Davis Institutional Review Board approved the study protocol and consent form.

Data collection

After obtaining informed consent and permission to access medical records, a trained research assistant conducted the prenatal interviews in person in the participants' preferred language (English or Spanish). The prenatal interviewer gathered data on socioeconomic measures, depressive symptoms (16), and infant feeding attitudes and intentions. Details regarding the screening process and prenatal interview are provided in an earlier publication (17).

A separate team of research assistants, masked to prenatal interview responses (including feeding intentions), conducted the postnatal follow-up interviews. Each participant was contacted within 24 h of giving birth to determine follow-up eligibility on the basis of: *1*) term infant, *2*) no separation of mother or infant >24 h anticipated (such as placement in the special care nursery), and *3*) mother initiated, or planned initiation of, breastfeeding (defined as offering the infant the breast at least once). Follow-up occurred via face-to-face interviews on days 0 (6–24 h postpartum), 3 (72–96 h postpartum), and 7 (1 wk from the day of birth) and subsequently via telephone interview.

At the day 0 visit, participants were asked about their labor and delivery experience and about breastfeeding, including any breastfeeding problems or concerns, formula and pacifier use, nipple type (everted, flat, or inverted), and degree of pain experienced in the nipples and breast. Two scores were recorded for each of nipple and breast pain: *1*) maximal pain since birth and *2*) pain in relation to the most recent breastfeed using the Faces Pain Scale–Revised (18). If possible, the postnatal interviewer observed and rated a breastfeeding according to the Infant Breastfeeding Assessment Tool (IBFAT) (19). We repeated the day 0 interview questions and assessments at the day 3 and day 7 home visits. In addition, infant weight was measured on an electronic scale (±2 g, BabyWeigh; Medela Inc, McHenry, IL).

Assessment scale validity and other data collection details

The Faces Pain Scale was initially developed to assess pain in pediatric patients and consists of 6 faces ranging from an expression representing no pain (scale score = 0) to worst possible pain (scale score = 5). The scale is strongly correlated with visual analog scale responses of children aged 5–12 y ($r = 0.93$, $n = 76$ nonclinical participants; $r = 0.92$, $n = 45$ clinical participants) (18). We pilot tested scale validity in English-speaking ($n = 90$) and Spanish-speaking ($n = 45$) low-income mothers (median age of infant: 6 wk) by presenting the faces as 6 individual unlabeled cards and asking the women to place the cards in order from no pain to maximum pain. Among English-speaking mothers, 80–95% of subjects within each ethnic group correctly ordered the faces; 95–99% of participants in each ethnic group were within one level of the correct order (ie, no more than one pair of neighboring cards were transposed, predominantly the middle 2 levels). Among Spanish-speaking mothers, 60% correctly ordered the faces and 85% had no more than one pair of neighboring cards transposed.

The IBFAT scores breastfeeding behavior on a scale of 1–12 on the basis of the observer's ratings for arousal, rooting, latch, and suck (for each, 0 = did not exhibit behavior to 4 = fully exhibited behavior). Interrater reliability was reported to be 91% in the initial validation of the IBFAT (20). The first author, who is an International Board–certified lactation consultant, trained the postnatal interviewers in conducting the IBFAT assessment. Interviewers were considered "standardized" in using the IBFAT when 90% agreement with the first author was achieved in classifying suboptimal breastfeeding behavior in >10 consecutive observations.

We assessed the timing of stage II OL as described previously (5). Briefly, each participant was asked at the day 3 interview to describe when her breasts felt "noticeably fuller" by using a numeric scale anchored with 1 = no change since giving birth, 3 = noticeably fuller, and 5 = uncomfortably full. For participants who had not experienced "noticeable fullness" or were unsure by the time of the day 3 interview, the question was repeated at the day 7 interview. We defined delayed OL as maternal perception of onset of noticeable fullness after 72 h postpartum.

At the day 7 visit, the postnatal interviewer used an L-square ruler (with a level indicator and a flat base that rested atop the head), a metal tape measure to measure the participant's height to the nearest 0.1 cm, and a digital scale to measure weight to the nearest 0.1 kg. Maternal and infant scales were checked for accuracy before each home visit by using standard weights. We confirmed the accuracy of the UCDMC birth-weight scales quarterly. At the day 7 interview, we asked participants to estimate

TABLE 1
Distribution of participant characteristics and prevalence of delayed onset of lactogenesis (OL)

Variable dimension and independent variables	No. in category	Prevalence of delayed OL (95% CI)	*P* value[1]
		%	
Overall	431	44.3 (39.6, 49.0)	
1) Maternal prenatal characteristics			
Age			
<30 y	313	39.0 (33.5, 44.4)	
≥30 y	118	58.5 (49.5, 67.5)	0.0003
Educational level			
<4-y college degree	173	37.0 (29.7, 44.3)	
≥4-y college degree	258	49.2 (43.1, 55.4)	0.012
Ethnicity			
Asian	53	47.2 (33.3, 61.1)	
African American	62	35.5 (23.2, 47.7)	
Hispanic with English as primary language	64	48.4 (35.9, 61.0)	
Hispanic with Spanish as primary language	54	35.2 (22.0, 48.3)	
White non-Hispanic	173	46.8 (39.3, 54.3)	
Identifies with >1 ethnic group	25	52.0 (31.0, 73.0)	0.365
Health insurance status			
Private	218	49.1 (42.4, 55.8)	
Public (Medi-Cal)	209	39.2 (32.6, 45.9)	0.041
Smoked during pregnancy			
No	395	44.6 (39.6, 49.5)	
Yes	26	38.5 (18.4, 58.5)	0.544
Excessive depressive symptoms[2]			
No	353	43.9 (38.7, 49.1)	
Yes	78	46.2 (34.8, 57.5)	0.718
Prenatal breast enlargement			
None	30	56.7 (37.8, 75.5)	
A little	231	44.6 (38.1, 51.0)	
A lot	170	41.8 (34.3, 49.3)	0.315
Breastfeeding self-efficacy[3]			
Weak	132	45.5 (36.8, 54.1)	
Moderate	142	47.9 (39.6, 56.2)	
Strong	157	40.1 (32.4, 47.9)	0.383
Intentions to provide only breast milk to 6 mo[4]			
Weak	33	54.5 (36.6, 72.5)	
Moderate	74	44.6 (33.0, 56.2)	
Strong	135	47.4 (38.9, 55.9)	
Very strong	189	40.2 (33.2, 47.3)	0.360
2) Maternal anthropometric characteristics (assessed at day 7 postpartum)			
Height			
<158.8 cm	145	37.9 (29.9, 45.9)	
158.8–165.0 cm	136	48.5 (40.0, 57.0)	
>165.0 cm	148	45.9 (37.8, 54.1)	0.172
BMI			
<25.0 kg/m^2 (underweight or normal)	121	31.4 (23.0, 39.8)	
25.0–29.9 kg/m^2 (overweight)	154	44.8 (36.9, 52.7)	
>30.0 kg/m^2 (obese)	130	53.8 (45.2, 62.5)	0.0015
Bra cup size			
A–B	73	43.8 (32.2, 55.5)	
C	114	43.0 (33.8, 52.2)	
D	98	42.9 (32.9, 52.8)	
DD–H	104	48.1 (38.3, 57.8)	0.858
Montgomery gland endowment in left breast			
Below median	188	42.6 (35.4, 49.7)	
Median or above	196	45.4 (38.4, 52.4)	0.573
3) Labor and delivery experience			
Delivery mode			
Vaginal	295	40.7 (35.0, 46.3)	
Cesarean	134	53.0 (44.4, 61.5)	0.018

(Continued)

TABLE 1 (*Continued*)

Variable dimension and independent variables	No. in category	Prevalence of delayed OL (95% CI)	*P* value[1]
		%	
Pitocin use			
None	185	47.0 (39.8, 54.3)	
Used to induce labor	99	43.4 (33.5, 53.4)	
Used to augment labor	128	40.6 (32.0, 49.2)	
Used to both induce and augment labor	17	52.9 (26.5, 79.4)	0.617
Labor pain management in vaginal births			
None	40	40.0 (24.1, 55.9)	
Epidural	222	41.9 (35.4, 48.4)	
Intravenous analgesia	17	29.4 (5.3, 53.6)	
Epidural and intravenous	15	40.0 (11.9, 68.1)	0.792
Duration of labor without pitocin to induce or augment labor			
<14 h	84	35.7 (25.3, 46.2)	
≥14 h	100	57.0 (47.1, 66.9)	0.004
Duration of labor with pitocin to induce or augment labor			
<14 h	87	47.1 (36.4, 57.8)	
≥14 h	157	40.1 (32.4, 47.9)	0.290
Stage II labor, vaginal births			
≤1 h	152	39.5 (31.6, 47.3)	
>1 h	134	41.0 (32.6, 49.5)	0.787
Interval without sleep before delivery			
≤18 h	214	46.3 (39.5, 53.0)	
>18 h	217	42.4 (35.8, 49.0)	0.419
Pain experienced during childbirth[5]			
None, mild, or moderate (score = 0–3, respectively)	56	44.6 (31.2, 58.1)	
Severe but not worst ever (score = 4)	81	40.7 (29.8, 51.7)	
Worst pain ever (score = 5)	294	45.2 (39.5, 51.0)	0.770
Intrapartum fluid balance			
<100 mL/h	100	48.0 (38.0, 58.0)	
100–200 mL/h	93	46.2 (35.9, 56.6)	
>200 mL/h	86	51.2 (40.4, 61.9)	0.801
Blood loss during delivery			
≤500 mL	240	42.1 (35.8, 48.4)	
>500 mL	115	49.6 (40.3, 58.8)	0.184
Mother and infant experienced skin-to-skin contact			
Yes	149	41.6 (33.6, 49.6)	
No	281	45.6 (39.7, 51.4)	0.434
4) Infant characteristics at birth			
Sex			
Female	219	42.5 (35.9, 49.1)	
Male	212	46.2 (39.5, 53.0)	0.432
Birth weight			
≤3600 g	304	38.2 (32.7, 43.6)	
>3600 g	127	59.1 (50.4, 67.7)	<0.0001
Gestational age			
37.0–38.9 wk	98	41.8 (31.9, 51.8)	
39.0–39.9 wk	151	47.0 (39.0, 55.1)	
40.0–42.3 wk	176	43.8 (36.3, 51.2)	0.701
One-minute Apgar score			
<8	101	51.5 (41.6, 61.4)	
≥8	317	42.0 (36.5, 47.4)	0.093
Five-minute Apgar score			
<9	66	51.5 (39.1, 63.9)	
≥9	351	42.5 (37.3, 47.6)	0.173
Oxygen support			
None	275	44.0 (38.1, 49.9)	
Free-flowing oxygen	113	46.9 (37.6, 56.2)	
Mask or more	26	42.3 (22.0, 62.7)	0.845

(Continued)

TABLE 1 (*Continued*)

Variable dimension and independent variables	No. in category	Prevalence of delayed OL (95% CI)	*P* value[1]
		%	
Amniotic fluid appearance			
Clear	320	45.0 (39.5, 50.5)	
Colored	80	40.0 (29.0, 51.0)	0.420
5) Maternal factors, days 0–3 postpartum			
Edema: peak level in first 48 h			
None	185	34.6 (27.7, 41.5)	
Edema with no or mild pitting	181	49.2 (41.8, 56.5)	
Edema with moderate to severe pitting	60	60.0 (47.2, 72.8)	0.0006
Nipple type at day 0			
Both everted	332	44.0 (38.6, 49.3)	
Flat or inverted	96	45.8 (35.7, 56.0)	0.747
Nipple type at day 3			
Both everted	321	43.9 (38.5, 49.4)	
Flat or inverted	98	40.8 (30.9, 50.7)	0.587
Nipple pain, peak since birth at day 0 interview[5]			
Mild (score = 0–1)	274	47.8 (41.9, 53.8)	
Moderate (score = 2–3)	70	40.0 (28.2, 51.8)	
Severe (score = 4–5)	83	34.9 (24.5, 45.4)	0.089
Nipple pain, peak since previous interview at day 3[5]			
Mild (score = 0–1)	108	53.7 (44.1, 63.3)	
Moderate (score = 2–3)	88	44.3 (33.7, 54.9)	
Severe (score = 4–5)	224	38.4 (32.0, 44.8)	0.031
Nipple shield use, since birth at day 3 interview			
No	327	44.6 (39.2, 50.1)	
Yes	95	40.0 (30.0, 50.0)	0.421
6) Infant feeding and related variables			
Timing of first breastfeed			
<2 h	334	44.3 (39.0, 49.7)	
>2 h	94	43.6 (33.4, 53.8)	0.905
Breastfeeding during 0–24 h			
<8 times	98	43.9 (33.9, 53.9)	
8 or 9 times	139	42.4 (34.1, 50.8)	
10–12 times	137	47.4 (39.0, 55.9)	
13–18 times	48	37.5 (23.3, 51.7)	0.656
"Breastfed well" during 0–24 h			
0 or 1 time	60	65.0 (52.6, 77.4)	
2–5 times	159	42.8 (35.0, 50.5)	
≥6 times	209	38.8 (32.1, 45.4)	0.0014
Formula use during 0–24 h			
None	297	43.4 (37.8, 49.1)	
0–60 mL	101	42.6 (32.8, 52.4)	
>60 mL	33	57.6 (39.8, 75.4)	0.277
"Breastfed well" during 24–48 h			
0 or 1 time	52	61.5 (47.9, 75.2)	
2–5 times	130	40.0 (31.5, 48.5)	
≥6 times	244	42.6 (36.4, 48.9)	0.023
Formula use during 0–48 h			
None	228	42.5 (36.1, 49.0)	
0–60 mL	109	36.7 (27.5, 45.9)	
>60 mL	94	57.4 (47.3, 67.6)	0.0090
Pacifier used in previous 24 h at day 3 interview			
No	198	41.4 (34.5, 48.3)	
Yes	220	45.0 (38.4, 51.6)	0.460
Suboptimal breastfeeding behavior at day 0 interview[6]			
No	161	39.8 (32.1, 47.4)	
Yes	266	46.6 (40.6, 52.7)	0.166
Suboptimal breastfeeding behavior at day 3 interview[6]			
No	299	41.1 (35.5, 46.7)	
Yes	121	48.8 (39.7, 57.8)	0.153

(Continued)

TABLE 1 (*Continued*)

Variable dimension and independent variables	No. in category	Prevalence of delayed OL (95% CI)	*P* value[1]
		%	
Breast-milk expression since birth at day 3 interview			
No	273	44.7 (38.8, 50.6)	
Yes	139	38.8 (30.6, 47.1)	0.257

[1] Derived by chi-square analysis.
[2] Defined as a score of ≥16 on the Center for Epidemiologic Study–Depression Scale.
[3] Breastfeeding Self-Efficacy Scale, short-form mean score (range: 1–4): weak, <3.0; moderate, 3.0–3.5; or strong, >3.5.
[4] Infant Feeding Intentions Scale (range: 0–16): weak, <8; moderate, 8–11.5; strong, 12–15.5; or very strong, 16.
[5] Faces Pain Scale: 0 = no pain to 5 = worst pain ever.
[6] Infant Breastfeeding Assessment Tool (score range: 0–12): suboptimal breastfeeding behavior defined as a score <11.

their current bra cup size (as a proxy for breast size) and the number of Montgomery glands (21) countable on the left breast.

To ensure accuracy in conducting the anthropometric measurements and consistency in recording participant responses for other aspects of the postnatal interviews, the first author shadowed all postnatal interviewers for ≥5 interviews and at least quarterly thereafter. In addition, the first author reviewed all postnatal interview forms for completeness and clarity within 1 wk of the interview.

The UCDMC has a breastfeeding policy consistent with the Ten Steps for Successful Breastfeeding (22). Mothers experiencing lactation difficulties during their maternity hospitalization are referred to the unit's nurse lactation consultant. On discharge, first-time breastfeeding mothers are offered an appointment with the UCDMC early breastfeeding follow-up clinic where they may receive lactation assistance during the first week postpartum. In addition to the data collected via interview, research assistants extracted data from the maternal and infant medical records related to the childbirth experience and maternity hospital stay, including labor and delivery interventions, type of delivery, maternal edema in the postpartum, breastfeeding progress, and infant formula supplementation. If maternal and medical record reports of volume of formula supplemented were discrepant, the larger volume was used.

Data analysis

We used Kaplan-Meier estimator methods (SAS Proc Lifetest; SAS Institute Inc, Cary, NC) to generate the survival distribution function for postpartum hour of maternal perception of onset of stage II lactogenesis. We used contingency tables and chi-square analysis to examine unadjusted associations between independent variables and the risk of delayed OL and organized the data into 6 dimensions: *1*) maternal prenatal characteristics, *2*) maternal anthropometric characteristics, *3*) labor and delivery experience, *4*) newborn characteristics, *5*) maternal postpartum factors, and *6*) infant feeding and related variables (**Table 1**). We collapsed self-identified ethnic group into 5 categories: African American, Asian, Hispanic (subdivided into English- and Spanish-speaking), non-Hispanic white, and "mixed" (the latter participants self-identified with >1 of the 4 major ethnic groups). We categorized educational level as ≤12 y (high school diploma or less) compared with >12 y (some college). We used health insurance status as a proxy for income level and categorized it as public or private insurance. Enrollment in the Special Supplemental Nutrition Program for Women, Infants, and Children was 90% concordant with income status; thus, this variable was not analyzed separately. We categorized maternal age as <30 and ≥30 y. We used the standard Center for Epidemiologic Studies–Depression Scale depressive symptom score of ≥16 to categorize participants as "at risk" of depression. The Infant Feeding Intentions Scale score was categorized as low (score range: 0–7.5), moderate (score range: 8–11.5), strong (score range: 12–15.5), and very strong (maximum score = 16) as described previously (23, 24). We calculated BMI as [maternal weight at day 7 postpartum (in kg)/maternal height (in m^2)] and categorized participants as normal/underweight, overweight, or obese on the basis of BMI < 25.0, 25.0–29.9, and 30.0, respectively (25).

To facilitate comparability with our earlier study, we categorized labor, delivery, and infant variables as described previously (*see* Table 1) (5). In addition to the labor and delivery variables examined in our previous report, we collected data on intrapartum fluid balance and postpartum edema status. For the former variable, 5 mo into our data collection period the UCDMC began a policy of documenting intrapartum fluid balance in the medical record, calculated as the net sum of the total amount of *fluid in* (oral and intravenous) minus the total amount of *fluid out* (void and emesis) from the time of admission to the labor and delivery unit until transfer out of the postpartum recovery room. Thus, for 285 (64%) of the study participants, this variable was available. Because we observed that net fluid balance was highly dependent on duration of the intrapartum interval, we calculated the average net fluid balance per hour in 3 categories: <100, 100–200, and >200 mL/h. In addition, our research assistants reviewed the postpartum flow sheet to record the nurse's assessment of postpartum edema. The highest level of edema (none; edema but no pitting; 1, 2, or ≥3 pitting edema) noted for each 24-h interval from birth to hospital discharge was recorded.

Nipple discomfort was categorized as none or mild, moderate, or severe on the basis of responses of 0–1, 2–3, or 4–5, respectively, on the Faces Pain Scale. We defined suboptimal breastfeeding behavior as scoring ≤10 (out of 12 points possible) on the IBFAT, consistent with our previous reports (5, 26).

After examining the unadjusted, bivariate associations with delayed OL, we used logistic regression analysis to estimate the adjusted odds ratio (OR) and 95% CI in multiple variable models.

We built our models in steps on the basis of significant variables in each of the dimensions shown in Table 1. For example, first we examined maternal prenatal characteristics associated with delayed OL (dimension 1 variables) and carried over to the next step only those variables significant at $P < 0.10$ in this initial adjusted model. We then added the maternal anthropometric variables (dimension 2 variables) that remained significant in the adjusted model, and so on. We checked for instances where the overall logistic regression model was significant but individual variables were not, due to excessive colinearity. The final logistic regression model was then reexamined after adjustment for prenatal feeding intentions. A known characteristic of the OR is that it approximates the RR only when the outcome is rare (<5% prevalence). With more common outcomes, the OR deviates markedly from RR (27). Given that the prevalence of our outcome (delayed OL) is >5%, to assist in the interpretation of results by readers we also included an estimate of the RR for each variable in the final logistic regression model by using the method proposed by Kleinman and Norton (28). All analyses were performed by using SAS version 9.2 (SAS Institute Inc).

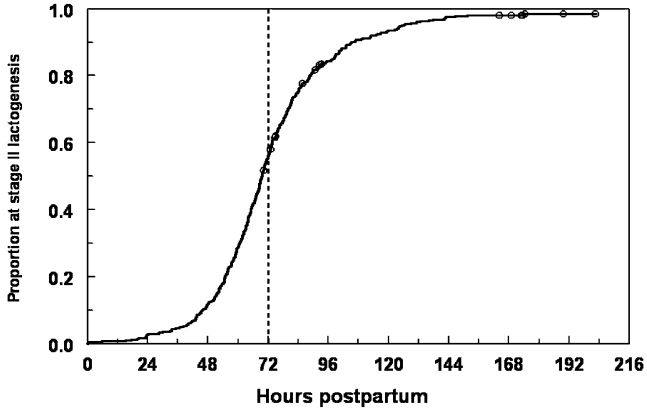

FIGURE 1. Cumulative distribution curve adjusted for censoring (100-survival distribution function, Kaplan-Meier estimator method) showing the postpartum hour of maternal perception of onset of lactogenesis (OL) (n = 431, including 15 censored values (○): 8 participants had not experienced OL at the time of the day 3 interview and were lost to follow-up on this outcome, and another 7 participants had not experienced OL at the time of the day 7 interview, which was the final time point OL was assessed.

RESULTS

Study cohort characteristics

Over the 24 mo of study enrollment, 768 of the women we screened met the eligibility criteria and 532 of these women agreed to the prenatal interview (69% of those eligible). Acceptance rates varied significantly by ethnic category (P = 0.0003). Listed from highest to lowest, acceptance rates were as follows: Spanish-speaking Hispanic, 81%; African American; 73%; white non-Hispanic, 72%; mixed ethnicity, 70%; English-speaking Hispanic, 70%; and Asian, 52%. However, acceptance rates were not significantly different by educational level (P = 0.22). Reasons for refusal were too busy (51%), not interested (25%), study too intrusive (18%), don't want to be interviewed about breastfeeding (3%), and miscellaneous (2%).

Of the 532 women we enrolled prenatally, 40 (7.5%) were lost to follow-up before delivery and 44 became ineligible for continued follow-up postdelivery (preterm birth, n = 11; mother and infant separated beyond the first 24 h, n = 21; and mother chose not to initiate breastfeeding, n = 12). Between the day 0 and day 3 interviews, an additional 11 participants declined to continue and an additional 6 went to live with a relative outside the catchment area, resulting in 431 with information on delayed OL (96% of those eligible at day 0). Of these, anthropometric data are missing for 26 women who were interviewed on day 7 via telephone rather than in person.

Characteristics of this study cohort (n = 431) are shown in Table 1. Overall, 51% of study participants had public health insurance (Medi-Cal), which was our criterion for low income. Mean (±SD) maternal BMI and birth weight were 28.7 ± 6.2 and 3295 ± 665 g, respectively.

Timing of stage II OL

The timing of maternal perception of onset of stage II lactogenesis for the entire study cohort is shown in **Figure 1**. Forty-four percent of participants had not yet perceived OL by 72 h postpartum, and 1.7% had not yet perceived OL by the time of the day 7 interview.

Unadjusted and adjusted associations with delayed OL

The unadjusted, bivariate associations with delayed OL are shown in Table 1. Maternal prenatal characteristics (dimension 1 variables) associated with delayed OL were greater maternal age, educational level, and income. However, in a model adjusted for all 3 of these characteristics, only maternal age (≥30 y) remained a significant risk factor ($P < 0.05$). Among the maternal anthropometric (dimension 2) variables, only greater BMI was associated with delayed OL, and this relation remained significant in a model adjusted for maternal age.

Among the labor and delivery variables (dimension 3), cesarean delivery was significantly associated with delayed OL in bivariate analysis but not after adjustment for maternal age and BMI. There was an interaction between duration of labor and prepartum pitocin use. Shorter duration of labor was significantly associated with decreased risk of delayed OL but only among women who did not receive pitocin to induce or augment labor. This relation remained significant in a model adjusted for maternal age and BMI but not after additional adjustment for infant birth weight. Among newborn characteristics (dimension 4), higher birth weight and lower 1-min Apgar score were associated with delayed OL; birth weight >3600 g remained a significant risk factor in a model adjusted for maternal age and BMI.

Maternal factors assessed over the first 3 d postpartum (dimension 5 variables) associated with delayed OL were presence of edema in the first 48 h postpartum and lack of nipple discomfort, as assessed at the day 0 and day 3 interviews. Edema exhibited strong colinearity with maternal BMI. For example, of the 56 women experiencing pitting edema (≥2), 53 were overweight or obese. Because it was not possible to examine the independent effects of BMI and edema in the same logistic regression model, these variables were examined in separate models. However, by using Mantel-Haenszel weighted chi-square analysis, the relation between edema severity and delayed OL remained significant when stratified by BMI category

($P < 0.05$), and the relation between BMI and delayed OL remained significant when stratified by edema severity ($P < 0.05$).

Lack of any nipple discomfort (Faces Pain Scale Score = 0 or 1) between the day 0 and day 3 interviews remained a significant risk factor in a model with maternal age, BMI, and birth weight. With respect to the infant feeding variables (dimension 6), delayed OL was inversely associated with the number of times that the infant "breastfed well" in the first 24 h and between 24 and 48 h of life and was positively associated with the amount of formula consumed over the first 48 h of life. As expected, these variables were strongly colinear. Frequency of "breastfed well" in the first 24 h was selected for inclusion in multivariate models because it is directly related to degree of nipple stimulation and breast emptying and its relation to delayed OL is less likely to be due to reverse causality as compared with the other 2 infant feeding variables.

Results for the final multivariate logistic regression model that included maternal BMI (n = 394 with complete data) are summarized in **Table 2**. In this model maternal age ≥30 y, maternal overweight or obesity, infant birth weight >3600 g, lack of infant "breastfeeding well" ≤2 times in the first 24 h, and absence of any nipple discomfort over the first 3 d postpartum were all independently associated with delayed OL. The addition of the Infant Feeding Intentions score to the model strengthened the association with maternal age and BMI, with little effect on the other variables.

Results for the same multivariate logistic regression model shown in Table 2 are summarized in **Table 3** but with maternal postpartum edema (n = 412) replacing maternal BMI. In this model, maternal age ≥30 y, infant birth weight >3600 g, and lack of infant "breastfeeding well" were all independently associated with delayed OL, but the absence of any nipple discomfort was no longer significant (adjusted OR: 1.51; 95% CI: 0.93, 2.45). Edema was only significant once Infant Feeding Intentions score was added to the model. Excluding nipple discomfort had little effect on the other variables in the model.

Homogeneity of relations between obesity and delayed OL across ethnic groups

After observing a strong relation between maternal BMI category and prevalence of delayed OL, we conducted a post hoc analysis of this relation stratified by ethnic group. The RR (95% CI) of delayed OL among obese (BMI ≥ 30.0) compared with normal weight (BMI < 25.0) women by ethnic group was as follows: African American, 1.0 (0.4, 2.6); Asian, 1.4 (0.6, 3.5); Hispanic, 2.0 (1.1, 3.8); and white, 2.3 (1.4, 3.7). In comparing this relation in African American with other ethnic groups combined, the Breslow-Day test for homogeneity of the OR was not significant (chi-square value = 2.4, P = 0.12) but tended toward rejection of homogeneity.

Consequences of delayed OL

As reported elsewhere, among the 227 infants who received <60 mL of formula during the first 3 d of life, the risk of excess weight loss (defined as >10% loss of birth weight at the day 3 interview) was 4.4 times greater if the mother experienced delayed OL (34.1% compared with 7.8% prevalence, $P < 0.0001$) (15, 29). To examine whether the perception of delayed OL was biased by maternal BMI status, we reexamined this relation stratified by maternal obesity. The RR of excess neonatal weight loss associated with delayed OL was similar and significant in both nonobese and obese women (**Figure 2**). The prevalence of suboptimal infant breastfeeding behavior, as assessed at the day-7 interview, and use of any infant formula on days 3–7 were

TABLE 2
Logistic regression model (with BMI) estimating odds of delayed onset of lactogenesis[1]

Variable	Reference level	OR (95% CI)[2]	AOR (95% CI)[3]	AOR (95% CI)[4]	ARR (95% CI)[5]
Maternal age					
≥30 y	<30 y	2.19 (1.40, 3.42)	2.48 (1.54, 4.01)	2.83 (1.72, 4.66)	1.62 (1.30, 2.01)
Maternal BMI					
25.0–29.9 kg/m^2	<25.0 kg/m^2	1.69 (1.02, 2.80)	1.78 (1.04, 3.04)	1.84 (1.07, 3.16)	1.40 (1.05, 1.92)
≥30.0 kg/m^2	<25.0 kg/m^2	2.55 (1.52, 4.30)	2.07 (1.17, 3.66)	2.21 (1.24, 3.94)	1.52 (1.13, 2.11)
Birth weight					
>3600 g	≤3600 g	2.49 (1.59, 3.88)	2.27 (1.41, 3.65)	2.28 (1.42, 3.69)	1.49 (1.19, 1.85)
"Breastfed well" (0–24 h)[6]					
0 or 1 time	≥2 times	2.63 (1.44, 4.82)	2.14 (1.11, 4.12)	2.02 (1.04, 3.92)	1.37 (0.98, 1.82)
Peak nipple pain[7]					
None or mild	Moderate–severe	1.93 (1.22, 3.05)	1.82 (1.11, 2.99)	1.81 (1.10, 2.98)	1.32 (1.04, 1.66)
Overall model					
AIC value	—	—	501	501	—
LR chi-square	—	—	51.1	56.9	—
P value	—	—	<0.0001	<0.0001	—

[1] OR, odds ratio; AOR, adjusted OR; ARR, adjusted relative risk; AIC, Akaike Information Criterion; LR, likelihood ratio.
[2] Unadjusted; n = 394 with values for all variables in the adjusted model.
[3] Adjusted for all other variables in the model shown (n = 394).
[4] Adjusted for all other variables in the model shown plus Infant Feeding Intentions score.
[5] Adjusted full model with Infant Feeding Intentions score (28).
[6] According to maternal assessment (well, fair, or poor) in the newborn flow sheet.
[7] From the day 3 interview, peak pain experienced since the day 0 interview according to the Faces Pain Scale: none or mild (0 or 1) or moderate–severe (2–5).

TABLE 3
Logistic regression model (with maternal edema) estimating odds of delayed onset of lactogenesis[1]

Variable	Reference level	OR (95% CI)[2]	AOR (95% CI)[3]	AOR (95% CI)[4]	ARR (95% CI)[5]
Maternal age					
≥30 y	<30 y	2.18 (1.40, 3.38)	2.14 (1.35, 3.41)	2.40 (1.49, 3.88)	1.62 (1.30, 2.01)
Maternal edema[6]					
Edema with 0 or 1 pitting	No edema	1.83 (1.19, 2.81)	1.50 (0.96, 2.35)	1.58 (1.00, 2.50)	1.40 (1.05, 1.92)
Edema with ≥2 pitting	No edema	2.81 (1.53, 5.16)	1.86 (0.97, 3.58)	2.03 (1.04, 3.96)	1.52 (1.13, 2.11)
Birth weight					
>3600 g	≤3600 g	2.38 (1.55, 3.67)	2.21 (1.40, 3.47)	2.24 (1.42, 3.54)	1.49 (1.19, 1.85)
"Breastfed well" at 0–24 h[7]					
0 or 1 time	≥2 times	2.90 (1.62, 5.20)	2.39 (1.28, 4.47)	2.28 (1.21, 4.29)	1.37 (0.98, 1.82)
Peak nipple pain[8]					
None or mild	Moderate–severe	1.69 (1.08, 2.64)	1.51 (0.94, 2.45)	1.51 (0.93, 2.45)	1.32 (1.04, 1.66)
Overall model					
AIC value	—	—	529	528	—
LR chi-square	—	—	48.1	55.3	—
P value	—	—	<0.0001	<0.0001	—

[1] OR, odds ratio; AOR, adjusted OR; ARR, adjusted relative risk; AIC, Akaike Information Criterion; LR, likelihood ratio.
[2] Unadjusted; $n = 412$ with values for all variables in the adjusted model.
[3] Adjusted for all other variables in the model shown ($n = 412$).
[4] Adjusted for all other variables in the model shown plus Infant Feeding Intentions category.
[5] Adjusted full model with Infant Feeding Intentions score (28).
[6] Peak level over the first 48 h postpartum.
[7] According to maternal assessment (well, fair, or poor) in the newborn flow sheet.
[8] From the day 3 interview, peak pain experienced since day 0 interview according to the Faces Pain Scale: none or mild (0 or 1) or moderate–severe (2–5).

significantly greater among infants of mothers with delayed compared with timely OL (**Figure 3**).

DISCUSSION

We observed delayed OL to be common in this diverse cohort of first-time mothers delivering term infants, all of whom initiated breastfeeding. Forty-four percent did not experience OL until >72 h postpartum, but nearly all (98.3%) did within the first week. Thus, even though *delayed* OL was common, *failed* OL was not. Nonetheless, the short-term adverse consequences of delayed OL (excess neonatal weight loss, suboptimal infant breastfeeding behavior at day 7, and use of formula supplement) indicate that more attention needs to be paid to this phenomenon. We observed significant bivariate associations with delayed OL among all 6 risk factor dimensions. In multivariate analysis, independent risk factors for delayed OL were maternal age ≥30 y, maternal overweight or obesity, infant birth weight <3600 g, lack of infant "breastfeeding well" at ≥2 times in the first 24 h, and absence of any nipple discomfort during the first 3 d postpartum.

Although others have previously reported an association between heavier maternal weight and delayed OL, our analysis provides the strongest case for a biological relation. We had large enough numbers of overweight and obese women to examine risk separately in these BMI categories. We found a dose-response relation, with the adjusted odds of delayed OL being 1.84 times higher in overweight and 2.21 times higher in obese women, as compared with women with a BMI in the normal range. The relation was significant even after adjustment for prenatal feeding intentions, which may be weaker in obese women (30). Furthermore, we measured maternal height and weight directly. However, evidence of an underlying biological mechanism is weakened by the results of our post hoc analysis, which tended toward lack of homogeneity between African American and other ethnic groups. Kugyelka et al (31) conducted an analysis of the relation between maternal BMI category and breastfeeding exclusivity, stratified by black or Hispanic ethnicity. They reported that among women who initiated breastfeeding, maternal BMI in the obese range was significantly associated with lack of exclusive breastfeeding on hospital discharge in Hispanic women ($P < 0.05$) but not in black women. A limitation of our analysis (and of those by others) is the use of BMI as a proxy for body fatness. The relations of BMI to both percentage body fat and

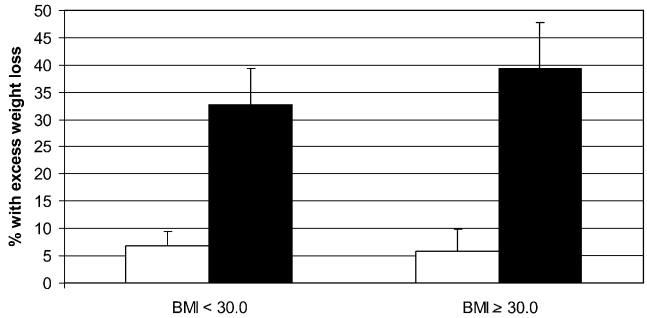

FIGURE 2. Prevalence (±SE) of excess neonatal weight loss (weight loss >10% of birth weight; restricted to infants consuming <60 mL of formula over the first 72 h; $n = 218$ with BMI data) by timing of onset of lactogenesis (OL), stratified by maternal BMI group. Numbers of participants in nonobese [BMI (in kg/m^2): < 30] and obese (BMI ≥ 30.0) groups, respectively, are as follows: timely OL (□; $n = 102$ and 34) and delayed OL (■; $n = 49$ and 33) [$P < 0.0001$ within the nonobese BMI group and $P = 0.001$ within the obese BMI group (chi-square analysis); Breslow-Day test for homogeneity of the odds ratios ($P = 0.6267$), indicating that there was not a significant difference by BMI group in the association between delayed OL and excess neonatal weight loss].

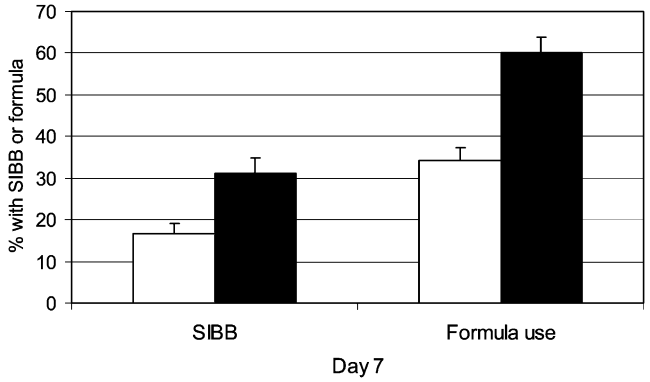

FIGURE 3. Prevalence (±SE) of suboptimal breastfeeding behavior (SIBB) at the day 7 interview or any formula use between days 3 and 6 by timing of onset of lactogenesis (OL). Numbers of participants evaluated for SIBB and formula use, respectively, are as follows: timely OL (□; n = 224 and 232) and delayed OL (■; n = 170 and 183) [P = 0.0006 for SIBB and $P < 0.0001$ for formula use (chi-square analysis)].

body fat distribution have been shown to vary across ethnic groups (32–34). Further research examining the effect of maternal fatness and body fat distribution on timing of OL with use of an a priori design powered to incorporate effect modification by ethnicity is needed.

To our knowledge, no one has previously reported a relation between older maternal age and delayed OL. Restricting our sample to first-time mothers may have allowed us to see this relation more clearly, because one would expect younger maternal age to be confounded by primiparity. High infant birth weight was also an independent risk factor for delayed OL. This finding is consistent with a previous observation in a different cohort of first-time mothers (5) but contradicts the findings reported by Chapman and Perez-Escamilla (6), who observed that birth weight <3.6 kg was a risk factor for delayed OL.

Despite collinearity between maternal age, BMI, and infant birth weight, all 3 variables were independently associated with delayed OL in a multivariate model. Both older maternal age and higher BMI are known risk factors for carbohydrate intolerance during pregnancy (35–37). Moreover, maternal glycemia level is the strongest predictor of large-for-gestational-age birth weight, even in nonpatients with diabetes (36). Disturbances in maternal glucose metabolism, such as increased insulin resistance or decreased insulin production, may be a key factor in the observed relations between older maternal age, larger birth weight, obesity, and delayed OL.

Failure of the infant to breastfeed well in the first 24 h and absence of nipple pain were independent predictors of delayed OL. Although severe nipple pain is a red flag for improper suckle at the breast, lack of any nipple pain may be related to weak or ineffective breastfeeding in some mother-infant pairs. The contribution of breast emptying or nipple stimulation to the timing of OL is not well established. Women who do not breastfeed at all in the early postpartum will still experience lactogenesis, but they are more likely to experience delayed OL (6). Breastfeeding frequency may be less important than the degree of nipple stimulation or breast emptying. In our cohort, several variables that likely reflect breastfeeding quality, either directly (lack of breastfeeding well in the first 24 or 48 h, absence of nipple discomfort at day 0 or day 3) or indirectly (formula use >60 mL over the first 48 h), were associated with delayed OL. In our previous cohorts, breastfeeding frequency in the early postpartum was not significantly associated with risk of delayed OL, but measures of breastfeeding quality were (5, 11).

Anecdotal reports from lactation consultants indicate that overweight or obese women, perhaps due to their larger breast size, have more difficulty positioning the newborn at the breast, and this may contribute to delayed OL and other breastfeeding difficulties. We did not observe a relation between bra cup size and risk of delayed OL (*see* Table 1). However, the percentages of infants who failed to "breastfeed well" ≥2 times in the first 24 h were 13%, 31%, and 56% among normal, overweight, and obese women, respectively (P = 0.0003). The latter relation was not modified by bra cup size (data not shown). Other factors associated with obesity, such as increased risk of cesarean delivery and postpartum edema, may pose challenges to effective breastfeeding in the first 24 h.

Limitations

As with all observational studies, our study had limitations. First, the timing of OL was on the basis of maternal perception, which arguably is a subjective assessment. However, the validity of using maternal perception to assess OL is supported by the strong association we observed between delayed OL and excess neonatal weight loss, irrespective of obesity status. This finding is consistent with our previous work (4, 5) and that of others (3, 38). Second, in previous studies in which we recruited mothers delivering at a variety of birth hospitals, we observed significant relations between birth experience variables (eg, cesarean delivery, longer duration of labor, and increased cortisol concentrations) and risk of delayed OL (4, 5). All of the participants in the present cohort gave birth at the UCDMC. Lack of variability in maternity care practices may have limited our ability to examine obstetric factors related to delayed OL. For example, only 42 women (9% of the sample) did not have medication to manage labor pain.

Conclusions

From a clinical perspective, primiparas who are older, overweight, or who give birth to an infant >3600 g are at greater risk of delayed OL and thus should be provided with appropriate lactation support until lactogenesis has occurred and the infant is gaining well. From a public health perspective, our results add to the growing evidence base regarding the negative consequences of maternal obesity on outcomes in both the mother and offspring (39). In addition to maternal characteristics, the early breastfeeding experience also contributes to the timing of OL. Maternity care practices consistent with the Baby Friendly Hospital Initiative or other model hospital breastfeeding policies (40) should be followed to help the mother and infant effectively breastfeed within the first 24 h. Causal mechanisms underlying the relation between postpartum edema and delayed OL are unclear.

As we describe elsewhere, our results suggest that the prevalence of delayed OL has reached epidemic proportions in the United States (15). It is important to note that investigators in some settings outside the United States report markedly lower prevalence of delayed OL, suggesting that even though this outcome was common in our cohort and other US cohorts (5, 6,

11), it is not necessarily normal for our species (10, 11, 26, 38). The risk factors for delayed OL are multidimensional; thus, addressing this epidemic requires a multipronged approach that includes public health, obstetric, and maternity care stakeholders.

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The authors' responsibilities were as follows—LAN-R: contributed to the study conceptualization, design, data collection, statistical analysis and writing of the manuscript; CJC: contributed to the study design and data collection and provided constructive feedback on each draft of the manuscript; JMP: contributed to statistical analysis; RJC: contributed to the study design and data collection; and KGD: contributed to the study conceptualization and design and provided constructive feedback on each draft of the manuscript. None of the authors had any conflicts of interest to disclose.

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