

Provided for non-commercial research and education use.
Not for reproduction, distribution or commercial use.



This article appeared in a journal published by Elsevier. The attached copy is furnished to the author for internal non-commercial research and education use, including for instruction at the authors institution and sharing with colleagues.

Other uses, including reproduction and distribution, or selling or licensing copies, or posting to personal, institutional or third party websites are prohibited.

In most cases authors are permitted to post their version of the article (e.g. in Word or Tex form) to their personal website or institutional repository. Authors requiring further information regarding Elsevier's archiving and manuscript policies are encouraged to visit:

<http://www.elsevier.com/copyright>

Available online at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.elsevier.com/locate/JOPR

Original Article

A study of the factors affecting time to onset of lactogenesis-II after parturition

Mohammed Saji Salahudeen^{a,*}, Ansu Mary Koshy^{a,c}, Suchandra Sen^b^a Faculty and Research Assistant, College of Pharmacy, Gulf Medical University, Ajman, United Arab Emirates^b Department of Pharmacy Practice, KMCH College of Pharmacy (Affiliated to the Tamil Nadu Dr. MGR Medical University), Coimbatore 641014, India

ARTICLE INFO

Article history:

Received 18 August 2012

Accepted 4 November 2012

Keywords:

Lactogenesis

Pregnancy

Apgar score

Hypothyroidism

ABSTRACT

Background: Lactogenesis or the mode of formation of milk. Lactogenesis-II commences after delivery and is the initiation of plentiful milk secretion. Time to lactogenesis is defined as the number of hours between delivery and the time that the sign of a surge in milk production is first observed. If the onset of lactogenesis occurs 72 h postpartum, it is defined as delayed.

Objective: To identify different socioeconomic, demographic and delivery related factors that affect the time of onset of lactogenesis-II.

Design: Six months prospective observational study.

Participants: A total of 200 subjects were recruited into the study. Pregnant women within age limit of 18–65 years of age were included in the study.

Methods: The data were collected from various sources such as patient's case reports, treatment charts and also through direct patient interview. The significance of the factors affecting onset of lactogenesis-II were assessed by chi-square test. A *p*-value less than 0.05 were considered to be statistically significant.

Results: The study showed that factors like type of anesthesia, mode of delivery, body mass index, Apgar score, parity, age, education, number of breastfeeding, infant birth weight, hemoglobin level, pregnancy induced hypertension, gestational diabetes mellitus, hypothyroidism are risk factors for delayed onset of lactogenesis-II.

Conclusion: By anticipating delay in lactogenesis-II, because of above mentioned factors clinicians may be able to support nursing mothers and prevent hasty transitions to formula supplementation due to a misperception of insufficient milk production as opposed to a delay in lactogenesis.

Copyright © 2012, JPR Solutions; Published by Reed Elsevier India Pvt. Ltd. All rights reserved.

* Corresponding author. Present address: Faculty and Research Assistant, College of Pharmacy, Gulf Medical University, Ajman, United Arab Emirates. Tel.: +971 559383632 (mobile).

E-mail address: drmohdsaji@gmail.com (M.S. Salahudeen).

^c Both authors contributed equally.

0974-6943/\$ – see front matter Copyright © 2012, JPR Solutions; Published by Reed Elsevier India Pvt. Ltd. All rights reserved.

<http://dx.doi.org/10.1016/j.jopr.2012.11.015>

1. Introduction

Breast milk is the natural first food of babies and provides all the energy and nutrients that infant needs for first months of life.¹ Lactation is the process of milk formation or secretion in the breasts during the period following child birth referred as breastfeeding or nursing.² For offspring breastfeeding confers protection against both under nutrition and over nutrition during early childhood and may lower risk of developing obesity, hypertension, coronary vascular disease, diabetes later in life. Therefore breastfeeding is recommended as a preferred method of infant feeding for the first year of life or longer and exclusive breastfeeding is recommended for first six months.³

Lactogenesis or the mode of formation of milk is divided into two stages. Lactogenesis-I occurs during pregnancy and is the initiation of the synthetic capacity of the mammary glands. Lactogenesis-II commences after delivery and is the initiation of plentiful milk secretion.⁴ Time to lactogenesis is defined as the number of hours between delivery and the time that the sign of a surge in milk production is first observed.⁵ If the onset of lactogenesis occurs 72 h postpartum it is defined as delayed.^{6,7} A significant delay in lactogenesis may adversely influence the lactation. Some of the suggested risk factors for delayed or failed lactogenesis-II are primiparity; maternal obesity; medical conditions – gestational diabetes mellitus, pregnancy induced hypertension, hypothyroidism; stressful labor and delivery; unscheduled cesarean section⁸; delayed first breastfeed episode; low prenatal breastfeeding frequency; and breast surgery or injury.²

Breastfeeding should begin as soon as possible after birth and should continue every 2–3 h.⁹ Studies have shown that maternal age had no relation to lactogenesis time.^{7,10} Apgar score is a test that was designed to quickly evaluate a newborns physical condition after delivery and to determine any immediate need for extra medical or emergency care.¹¹

2. Materials and methods

The study was a prospective observational study conducted in the Department of Gynecology, at Kovai Medical Center and Hospital (KMCH), Coimbatore, Tamil Nadu, India for a period of six months from June 2011 to December 2011. The study protocol was approved by the Institutional Ethical Committee of Kovai Medical Center and Hospital (KMCH), Coimbatore, Tamil Nadu, India. Patients who were pregnant from June–December 2011 from 18 years of age were included in this study. The study was explained to the patients and their relatives and their oral consent was taken. Women with multiple births, premature delivery, post-partum hemorrhage, history of breast surgery, abnormal breast development during pregnancy or with inverted nipples were excluded from this study. The time of onset of lactogenesis was noted in pregnant patients who included the inclusion criteria's. Patient data's including weight, height, dietary habits, past medical and medication history, laboratory investigations, pregnancy related diseases, mode of delivery, weight of the baby, time of onset of lactogenesis, number of breastfeeds per day etc. The sources data were the patient's case reports, treatment charts and also through direct patient interview.

A total of 200 subjects who were satisfying the inclusion criteria were enrolled in the study. Significance of the factors affecting onset of lactogenesis-II were assessed by chi-square test. A *p*-value of less than 0.05 was considered to be statistically significant.

3. Results

In this prospective study the factors affecting onset of lactogenesis-II was evaluated among a total of 200 pregnant women admitted in Kovai Medical Center and Hospital during the period June 2011–December 2011.

The average time to lactogenesis was 66.95 h. A delayed onset of lactogenesis-II (≥ 72 h) was experienced by 50 (25%) women. Most women (47%) experienced pain at the time of reported onset of lactogenesis. Other breast symptoms include heaviness (17%), leakage (19%) and (17%) of women did not experience any breast symptoms.

3.1. Age

The mean age of patients was found to be 26 years. Ninety-seven (48.5%) patients were less than 26 years and the rest were elder. Out of 97 patients, 76 (38%) had normal onset of lactogenesis-II and 21 (10.5%) had delayed onset of lactogenesis-II. Out of 103 (51.5%) patients, 74 (37%) had normal and 29 (14.5%) had delayed onset of lactogenesis-II.

3.2. Educational status

On the basis of education level, patients were divided as undergraduate and graduate. A total no. of 39 (19.5%) patients were undergraduate and the rest were graduate. Out of 39 patients, 31 (15.5%) had normal and 8 (4%) had delayed onset of lactogenesis-II. Out of 161 (80.5%) graduates, 119 (59.5%) had normal and 42 (21%) had delayed onset of lactogenesis-II.

3.3. Parity

Out of 200 patients, 130 (65%) were primiparous and 70 (35%) were multiparous. In primiparous, 98 (49%) had normal and 32 (16%) had delayed onset of lactogenesis-II. In multiparous, 52 (26%) had normal and 18 (9%) had delayed onset of lactogenesis-II.

3.4. Body mass index

Body mass index which is an indicator of obesity was correlated. The patients were divided into ≤ 24 and >24 . 157 (78.5%) patients had ≤ 24 body mass index and 43 (21.5%) patients had >24 body mass index. Out of 157, 120 (60%) patients had normal and 37 (18.5%) had delayed onset of lactogenesis-II. Out of 43 obese patients, 29 (14.5%) had normal and 14 (7%) had delayed onset of lactogenesis-II showed in Table 1.

3.5. Mode of delivery

Normal delivery was the mode for 87 (43.5%) and elective, emergency cesarean section was done for 113 (56.5%) patients.

Table 1 – Association between body mass index and time of onset of lactogenesis-II.

Category	Number of patients	TOL-II (hours) Mean score (S.D.)	Time of onset of lactogenesis-II		OR	95% CI	p-Value
			Normal	Delayed			
≤24	157 (78.5%)	65.88 (14.21)	121 (60.5%)	36 (18%)	1.62	0.78–3.39	0.09
>24	43 (21.5%)	70.88 (18.05)	29 (14.5%)	14 (7%)			

Table 2 – Association between mode of delivery and time of onset of lactogenesis-II.

Category	Number of patients	TOL-II (hours) Mean score (S.D.)	Time of onset of lactogenesis-II		OR	95% CI	p-Value
			Normal	Delayed			
Normal	87 (43.5%)	62.89 (12.97)	74 (37%)	13 (6.5%)	0.36	0.18–0.73	0.002*
Cesarean	113 (56.5%)	70.08 (16.09)	76 (38%)	37 (18.5%)			

Out of 87 patients, 74 (37%) had normal and 13 (6.5%) had delayed onset of lactogenesis-II. Out of 113 patients, 76 (38%) had normal and 37 (18.5%) had delayed onset of lactogenesis-II illustrated in Table 2.

3.6. Anesthesia during pregnancy

Regional anesthesia (spinal) was used for cesarean delivery in 113 (56.5%) patients and in the rest 87 (43.5%) normal delivery patients' anesthesia was not used. Out of 113, 76 (38%) had normal and 39 (19.5%) had delayed onset of lactogenesis-II. Out of 87 normal delivery patients, 74 (37%) had normal and 13 (6.5%) had delayed onset of lactogenesis-II.

3.7. Infant birth weight

Normal weight of a new born baby is ≥2.5 kg. It was divided into two. Babies having <2.5 kg and ≥2.5 kg. 173 (86.5%) babies had ≥2.5 kg and 27 (13.5%) babies had <2.5 kg. Out of 173 babies, 135 (67.5%) had normal onset of lactogenesis-II and 38 (19%) had delayed onset of lactogenesis-II. Out of 27 babies, 14 (7%) had normal and 13 (6.5%) had delayed onset of lactogenesis-II.

3.8. Number of breastfeeding's

Number of breastfeeding data was collected from 130 (65%) patients. It was divided as ≥10 and <10 breastfeeds on the first day of postpartum. Among 130 cases, 56 (43%) women breastfed ≥10 times in the first day and 74 (56.9%) women breastfed <10 times in the first day. Out of 56 women, 46 (35.4%) had normal and 10 (7.7%) had delayed onset of lactogenesis-II. Out of 74 women, 59 (45.4%) had normal and

15 (11.5%) had delayed onset of lactogenesis-II. The p-value was not significant between different groups.

3.9. Apgar score

Apgar score which is a test that is designed to quickly evaluate a newborns physical condition after delivery was studied. It was estimated only in 97 (48.5%) patients. The score were divided into <7 and ≥7 (of the first minute). 89 (91.7%) babies had Apgar score ≥7 and 8 (8.24%) had <7. Out of 89, 71 (73.2%) had normal and 18 (18.5%) had delayed onset of lactogenesis-II. Out of 8, 5 (5.15%) had normal and 3 (3.09%) had delayed showed in Table 3.

3.10. Hemoglobin level

Anemia was identified by patients having hemoglobin level ≥12 (normal) and <12 (anemic) just before delivery. 134 (67%) were anemic and the rest 66 (33%) were not. Out of 134, 43 (21.5%) had normal and 23 (11.5%) had delayed onset of lactogenesis-II. Out of 66, 107 (53.5%) had normal and 27 (13.5%) had delayed onset of lactogenesis-II showed in Table 4.

3.11. Co-morbid conditions

Of the total population only 13 (6.5%) had pregnancy induced hypertension, 12 (6%) had gestational diabetes mellitus and 3 (1.5%) had hypothyroidism. Out of 13 pregnancy induced hypertension patients, 11 (5.5%) had delayed onset of lactogenesis-II. Out of 12 gestational diabetes mellitus patients, 7 (3.5%) had delayed onset of lactogenesis-II. Out of 3 hypothyroidism patients, 2 (1%) had delayed onset of lactogenesis-II showed in Table 5. Statistically each factor was

Table 3 – Association between Apgar score and time of onset of lactogenesis-II.

Category	Number of patients	TOL-II (hours) Mean score (S.D.)	Time of onset of lactogenesis-II		OR	95% CI	p-Value
			Normal	Delayed			
≥7	89	67.40 (15.42)	71 (73.19%)	18 (18.56%)	2.37	0.52–10.85	0.13
<7	8	69.36 (4.17)	5 (5.15%)	3 (3.09%)			

Table 4 – Association between hemoglobin level and time of onset of lactogenesis-II.

Category	Number of patients	TOL-II (hours) Mean score (S.D.)	Time of onset of lactogenesis-II		OR	95% CI	p-Value
			Normal	Delayed			
≥12	66 (33%)	70.6 (17.33)	43 (21.5%)	23 (11.5%)	0.47	0.24–0.91	0.01*
<12	134 (67%)	65.14 (13.76)	107 (53.5%)	27 (13.5%)			

Table 5 – Association between pregnancies induced hypertension, gestational diabetes mellitus, hypothyroidism and time of onset of lactogenesis-II.

Category	Number of patients	TOL-II (hours) Mean score (S.D.)	Time of onset of lactogenesis-II		OR	95% CI	p-Value
			Normal	Delayed			
PIH	13 (6.5%)	84.79 (15.46)	2 (1%)	11 (5.5%)	0.05	0.01–0.22	<0.0001*
No PIH	187 (93.5%)	65.71 (14.43)	148 (28%)	39 (19.5%)			
GDM	12 (6%)	83.19 (19.51)	5 (2.5%)	7 (3.5%)	0.21	0.06–0.70	0.003*
No GDM	188 (94%)	65.92 (14.34)	145 (72.5%)	43 (21.5%)			
Hypothyroidism	3 (1.5%)	76.45 (17.40)	1 (0.5%)	2 (1%)	0.16	0.01–1.81	0.04*
No hypothyroidism	197 (98.5%)	66.81 (15.18)	149 (74.5%)	43 (21.5%)			

Pregnancy induced hypertension (PIH), gestational diabetes mellitus (GDM).

analyzed. In this study it was found that mode of delivery, type of anesthesia, weight of baby, hemoglobin level, medical conditions – pregnancy induced hypertension, gestational diabetes mellitus, hypothyroidism had significant relation to the time of onset of lactogenesis. Factors like age, education, parity, body mass index, number of breastfeeding and Apgar score was found not to have any relation to the time of onset of lactogenesis.

4. Discussion

The study population consisted of 200 patients. Researchers have also indicated that there was no correlation between time of onset of lactogenesis-II and maternal age.⁷ The present study results suggest there was no significant relation between age and time of onset of lactogenesis-II.

Researchers have also indicated that parity did not appear to affect time of onset of lactogenesis-II. Association between parity and breastfeeding initiation is inconsistent.¹² But one other study reported that primiparity women are more likely to experience a delayed onset of lactation by an additional 11 h.⁷ The present study did not find any significant relation between parity and time of onset of lactogenesis-II.

Our research did not find any significant relation between body mass index and the time of onset of lactogenesis-II.¹³ Various studies have also concluded that cesarean section is linked with delayed onset of lactogenesis-II and excessive weight loss.^{2,6} Our research work revealed that mode of delivery had significant relation to the time of onset of lactogenesis-II.

The present study found significant relation between anemia and the time of onset of lactogenesis-II. Studies have concluded that it impairs the iron dependent tissue enzymes, affecting several metabolic processes, which might have a bearing on lactation in anemic mother.¹⁴ Our study found significant relation between pregnancy induced hypertension

and the time of onset of lactogenesis-II. Researchers have shown that women with pregnancy induced hypertension with or without antihypertensive experienced slightly longer time to lactogenesis. The use of antihypertensive immediately postpartum showed a trend to cause a further delay on time to lactogenesis.¹² Studies have concluded that gestational diabetes mellitus women had more difficulty expressing colostrums from their breasts during first two days of lactation resulting in delayed onset of lactogenesis-II.¹⁵ Our study found significant relation between gestational diabetes mellitus and the time of onset of lactogenesis-II. Our study found significant relation between hypothyroidism and the time of onset of lactogenesis-II. Studies have concluded in case of hypothyroidism delayed lactation or insufficient milk production occurred. In case of hyperthyroidism there was impairment of milk ejection; lactation was severely suppressed unable to express colostrums resulting in delayed onset of lactogenesis-II.¹⁶

5. Conclusion

Lactogenesis-II symbolizes a major infants feeding event because it is the point in time at which the mammary gland begins producing copious amount of milk. The study that we conducted was focused to assess patients having a significant delay in onset of lactogenesis-II and the factors responsible for delayed onset of lactogenesis-II. From our study it was revealed that mode of delivery, type of anesthesia, anemia, birth weight, medical conditions such as pregnancy induced hypertension, gestational diabetes mellitus, and hypothyroidism had significant relation to time to onset of lactogenesis-II. Delay in lactogenesis-II may adversely affect the lactation process, including breastfeeding duration. The results from this study may help to develop a profile of women at risk of delayed onset of lactogenesis-II and allow clinicians to target appropriate interventions and educating nursing

mothers on expectation and provide support and reassurance when delay to lactogenesis may be expected. By anticipating delay in lactogenesis-II, clinicians may be able to support nursing mothers and prevent hasty transitions to formula supplementation due to a misperception of insufficient milk production as opposed to a delay in lactogenesis. However the study results have to be validated in large population setup to confirm the results.

To conclude, the study has enabled to find out the factors affecting time of onset of lactogenesis-II and it may help clinicians to identify women at risk of delayed onset of lactogenesis-II and to give them proper support.

Conflicts of interest

All authors have none to declare.

Acknowledgment

The authors wish to thank all the faculty members of Department of Pharmacy Practice, KMCH College of Pharmacy, India for their valuable guidance. We extend our heartfelt thankfulness to KMCH Hospital medical staffs, Coimbatore, India for their timely support to complete this work.

REFERENCES

1. World Health Organization (WHO). *Indicator for Assessing Breastfeeding Practices*. Report of an informal meeting in June; 1991. Geneva.
2. Hurst NM. Recognizing and treating delayed or failed lactogenesis II. *J Midwifery Womens Health*. 2007;52:588.
3. Gunderson EP. Breastfeeding after gestational diabetes pregnancy and subsequent obesity, type two diabetes in women and off-spring. *Lancet*. 2002;360:187.
4. Hartmann P, Cregan M. Lactogenesis and the effects of insulin-dependent diabetes mellitus and prematurity. *J Nutr*. 2001;131:3016S.
5. Sakha K, Behbahan AGG. The onset time of lactation after delivery. *Med J Islamic Republic Iran*. 2005;19:135.
6. Chapman DJ, Escamilla PR. Association of infant weight and breastfeeding. *J Am Diet Assoc*. 1996;97:50.
7. Hildebrandt HM. Maternal perception of lactogenesis time: a clinical report. *J Hum Lact*. 1999;15:317.
8. Chapman DJ, Escamilla PR. Identification of risk factors of delayed onset of lactation. *J Am Diet Assoc*. 1999;99:450.
9. Hanson Lars A. *Immunobiology of Human Milk: How Breastfeeding Protects Babies*, vol. 15. Pharmasoft Publishing; 2004. 10.
10. Binns CW, Scott JA. Factors associated with the initiation and duration of breastfeeding: a review of the literature. *Aust J Nutr Diet*. 1998;55:51.
11. Mulford C. The mother baby assessment; an apgar score for breastfeeding. *J Hum Lact*. 1991;8:79.
12. Kong MS, Baeta Bajorek. Medications in pregnancy: impact on time to lactogenesis after parturition. *J Pharm Pract Res*. 2008;38:205.
13. Arendas K. Obesity in pregnancy: pre-conceptional to post-partum consequences. *J Lancet*. 2006;38:15.
14. Finch IA, Huebers H. Perspective in iron metabolism. *N Eng J Med*. 1982;306:1502.
15. Graf UM, Hartmann R, Pawliczak J, Passow D. Association of breastfeeding and early childhood overweight in children from mothers with gestational diabetes mellitus. *J Diabetes Care*. 2006;29:1005.
16. Marsoco MA. The impact of thyroid dysfunction on lactation. *J Breastfeed*. 2006;25:9.