Current Trends in Biotechnology and Pharmacy
Vol. 19 (Supplementary Issue 4), Oct-Dec 2025, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2025.4s.28

Patterns and Determinants of Prolonged Galactagogue use among Mothers of Preterm Infants: A Secondary Analysis of the FILM Trial

Urmila Umasekar[1]*, and Nalini Sirala Jagadeesh[2]

[1,2]Department of Obstetrics and Gynaecology Nursing, Sri Ramachandra Faculty of Nursing, Sri Ramachandra Institute of Higher Education and Research (DU), Chennai-600116,Tamilnadu, India

*Corresponding author: urmila.u@sriramachandra.edu.in

Abstract

Galactagogues are substances used to enhance breastmilk production in lactating mothers. They can be categorized into oral pharmaceutical drugs and powdered lactation supplements. While intended for short-term use, concerns arise regarding prolonged intake, particularly when prescribed on an as-needed basis. This study examines the prevalence, prescribing patterns, and factors influencing prolonged galactagogue use among mothers of preterm infants (27–34 weeks gestation).This study is a secondary analysis of data from the FILM trial (CTRI/2022/10/046204), focusing on control group participants. A prospective observational approach was used to collect data between January 2022 and September 2024 in a tertiary care hospital. A total of 110 mothers of singleton preterm infants (27–33^{6} weeks GA) were included. Data on galactagogue type (oral drug vs. powder form), initiation timing, dosage, prescribing patterns (routine vs. if necessary), and duration of use were analyzed. Logistic regression was performed to assess predictors of prolonged use, with results reported as adjusted odds ratios (AOR) and 95% confidence intervals (CI).Among 110 participants, 69 (62.7%) reported galactagogue use. Oral drugs were initiated at a median of 3 postnatal days (IQR: 2–5), while powdered supplements were commonly consumed once or twice daily. 31 (45.2%) of galactagogue users continued intake beyond prescription, and 20 (28.9%) used them without medical consultation. 27 (39.1%) of mothers who received SOS (if necessary) prescriptions transitioned to continuous use, citing concerns about milk supply. 45(65.3%) of galactagogue users inquired about discontinuation guidance. Mothers who received SOS prescriptions were 2.8 times more likely to continue using galactagogues beyond the prescribed duration (AOR 1.84, 95% CI: 1.32–6.10, p = 0.011). Additionally, mothers who perceived their milk supply as low were 3.2 times more likely to prolong use (AOR 2.21, 95% CI: 1.45–7.12, p = 0.004). Galactagogue use was common among preterm mothers, with a significant proportion continuing beyond prescription, particularly when prescribed on an SOS order. Uncertainty regarding discontinuation and maternal perceived low milk supply played key roles in prolonged use. Strengthening lactation counseling and clearer prescribing guidelines may help optimize galactagogue use and support maternal confidence in breastfeeding.

Keywords: Galactagogues, Preterm infants, Lactation, Breastfeeding

Introduction

Breastfeeding offers a multitude of health benefits for both infants and mothers, with particular significance for preterm infants due to their vulnerability to infections, necrotizing enterocolitis, and growth delays(1). The World Health Organization recommends exclusive breastfeeding for the first six months, and initiation within the first hour of birth. However, preterm births often interfere with immediate and sustained breastfeeding efforts due to maternal stress,

Vol. 19 (Supplementary Issue 4), Oct-Dec 2025, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2025.4s.28

medical complications, and neonatal separation in intensive care units (2).To overcome lactation challenges, galactagogues, the substances that enhance milk productionare commonly prescribed. These include pharmaceutical drugs like domperidone and metoclopramide, as well as herbal supplements and powdered formulations(3–5). While their efficacy remains a topic of debate, their usage is prevalent, especially among mothers of preterm infants with perceived or actual lactation insufficiencies. Most clinical guidelines recommend galactagogues only after non-pharmacological methods(1,2).

Despite recommendations for short-term use, prolonged galactagogue intake is increasingly reported. In clinical practice, many prescriptions are given with vague instructions or marked "SOS" (as needed), leading to extended use beyond clinical need. Such unmonitored usage raises concerns regarding dependency, reduced emphasis on proper lactation techniques, and potential side effects.

The Family Integrated Lactation Management (FILM) trial was designed to address various aspects of lactation challenges among mothers of preterm infants. This secondary analysis focuses on the control group, which did not receive structured lactation intervention. The objective of this study is to investigate the prevalence, patterns, and predictors of prolonged galactagogue use in this population. Identifying behavioral and clinical factors associated with extended usage can guide healthcare providers in developing clear protocols and support systems to optimize breastfeeding outcomes.

Materials and Methods

This is a secondary analysis of the FILM trial (CTRI/2022/10/046204), a prospective, randomized, controlled trial designed to improve breastfeeding outcomes in mothers of preterm infants. For this study, only the control group participants were analyzed to observe naturalistic galactagogue usage patterns without the influence of a structured lactation intervention.

Study Setting and Participants

The study was conducted at the neonatal intensive care unit (NICU) of a tertiary care teaching hospital in Chennai, India. Mothers who delivered singleton preterm infants (gestational age 27–34 weeks) between January 2022 and September 2024 were included. Exclusion criteria included multiple births, significant maternal or neonatal complications preventing breastfeeding initiation, or prior participation in lactation counseling programs.

Data Collection

Data were collected prospectively from medical records and structured interviews with mothers during their NICU stay and follow-up visits. A pretested questionnaire was used to gather details on sociodemographic characteristics, obstetric history, galactagogue usage (type, timing, dose, frequency, and prescribing pattern), and maternal perceptions regarding milk supply.

Prolonged galactagogue use was defined as consumption beyond seven days past the prescribed duration or continued use in the absence of a formal prescription. Prescriptions were categorized as "routine" (scheduled) or "SOS" (as needed).

Statistical Analysis

Descriptive statistics were used to summarize participant characteristics and galactagogue usage patterns. Categorical variables were reported as frequencies and percentages, continuous variables were presented as mean and standard deviation or median with interquartile range. Univariate logistic regression was used to screen potential predictors of prolonged use. Significant variables ($p < 0.05$) were entered into a multivariate logistic regression model. Adjusted odds ratios (AOR) with 95% confidence intervals (CI) were reported. All analyses were conducted using SPSS

Vol. 19 (Supplementary Issue 4), Oct-Dec 2025, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2025.4s.28

version 25. A p-value < 0.05 was considered statistically significant.

Ethical clearance for the FILM trial was obtained from the Institutional Ethics Committee, and informed consent was obtained from all participants.

Results

A total of 110 mothers of preterm infants were included in this secondary analysis of the FILM trial. The mean maternal age was 29.3+5.15years, with the majority (60.9%) being primiparous. Nearly three-quarters (74.5%) had delivered via cesarean section. Most infants were born between 32–34 weeks of gestation (53.6%), and the mean birth weight was 1.62±0.43 kg (Table 1).

Out of 110 mothers, 69 (62.7%) reported using galactagogues to enhance breast milk production. Among them, 49.3% used oral pharmaceutical galactagogues, 26.1% consumed powdered lactation supplements, and 24.6% used both types. The median postnatal day for first galactagogue use was day 3, with an interquartile range (IQR) of 2 to 5 days.

The leading reasons cited for initiating galactagogue use were maternal perception of inadequate milk supply (37.7%), followed by healthcare provider recommendation (23.2%), Inadequate milk expression despite regular pumping (13%), and delayed lactogenesis (8.7%) (Table 2). Mothers often attributed low milk supply to stress and fatigue and were more inclined to initiate or continue galactagogue use based on anecdotal advice or previous experiences.

Among the galactogogue users, 45.2% continued their use beyond the prescribed duration, indicating prolonged use. A considerable proportion (28.9%) initiated galactagogue use without prior medical

Table 1: Frequency and Percentage distribution of Baseline characteristics of mothers of preterm infants (N-110)

Baseline Characteristics	Frequency (n)	Percentage (%)
Maternal Age, (Mean±SD)	29.3±5.15	
Maternal education		
School	21	19.1
Graduate	87	79.1
Homemaker	78	70.9
Socio-Economic Status		
Upper Middle	32	29.1
Lower Middle	27	24.5
Upper Lower	51	46.4
Religion		
Hindu	87	79.1
Christian	14	12.7
Muslim	9	8.2
Nuclear family	49	44.5
Non-Vegetarian	98	89.1
Caesarean delivery	82	74.5
Primiparity	67	60.9
Gestational age at delivery 27-29^{6} weeks	23	20.9
30-31^{6} weeks	28	25.5
32-33^{6} weeks	59	53.6
Birth weight of the baby, (Mean±SD)	1.62±0.43	

Vol. 19 (Supplementary Issue 4), Oct-Dec 2025, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2025.4s.28

Table 2: Frequency and Percentage of Reasons for Starting Galactogogues in Mothers of Preterm Infants (N=69)

Primary Reason for Starting Galactogogue	n	%
Perceived low milk supply	26	37.7
Recommendation by healthcare provider	16	23.2
Inadequate milk expression despite regular pumping	9	13.0
Delayed initiation of breastmilk expression (>6 hrs)	7	10.1
Delayed onset of lactogenesis II (>72 hrs postpartum)	6	8.7
Pressure to meet NICU feeding targets	5	7.3

Table 3: Logistic Regression Analysis of Factors Associated with Prolonged Galactogogue Use (N = 69)

Variable	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
SOS (as-needed) prescription (vs routine)	2.10 (1.40 – 5.50)	0.008	1.84 (1.32 – 6.10)	0.011
Perceived low milk supply (yes vs no)	3.50 (1.80 – 7.00)	0.001	2.21 (1.45 – 7.12)	0.004
Inadequate expression despite pumping	1.80 (0.95 – 3.40)	0.075	1.56 (0.89 – 3.70)	0.108
Delayed initiation of expression (>6 hrs)	1.45 (0.80 – 2.90)	0.190	1.31 (0.76 – 2.91)	0.183
Delayed lactogenesis II (>72 hrs)	1.40 (0.70 – 2.70)	0.210	1.27 (0.65 – 2.50)	0.226
Pressure to meet NICU feeding targets	1.20 (0.65 – 2.60)	0.280	1.12 (0.58 – 2.34)	0.278

consultation, highlighting a trend of self-medication (Fig. 1).

Factors Associated with Prolonged Galactagogue Use

Multivariate logistic regression was conducted to identify determinants of prolonged galactagogue use among mothers of preterm infants (n = 69). After adjusting for potential confounders, two variables emerged as statistically significant predictors.SOS (as-needed) prescription was significantly associated with prolonged use compared to routine prescribing. Mothers who received SOS instructions had nearly twice the odds of continuing galactagogues beyond the intended duration (AOR= 1.84; 95% CI: 1. 32–6.10; p = 0.011).Maternal perception of low milk supply was the strongest predictor of prolonged use. Mothers who believed their milk supply was insufficient had over twice the odds of extended galactagogue intake (AOR = 2.21; 95% CI: 1.45–7.12; p = 0.004).

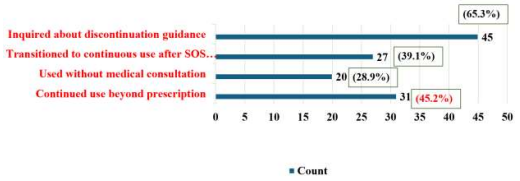

Fig. 1: Patterns of Galactogogue use among Mothers (N=69)

Other variables, including inadequate expression despite pumping, delayed initiation of expression beyond 6 hours, delayed lactogenesis II beyond 72 hours, and perceived pressure to meet NICU feeding targets, did not show statistically significant associations with prolonged galactagogue use (Table 3).

Overall, the findings underscore a pattern of unsupervised or prolonged galactagogue use influenced by subjective concerns, unclear prescription instructions, and limited postpartum lactation support. These results highlight the need for

Vol. 19 (Supplementary Issue 4), Oct-Dec 2025, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2025.4s.28

standardized prescribing practices and structured lactation counseling for mothers of preterm infants.

Discussion

The present study highlights a widespread use of galactagogues among mothers of preterm infants in a tertiary care setting, with nearly half of the users continuing these substances beyond the prescribed period. This finding underlines a critical gap in postpartum lactation guidance and the need for structured follow-up.

Our finding that 62.7% of mothers used galactagogues aligns with previous reports indicating high prevalence among mothers of preterm or low birth weight infants(5–7). In many cases, the use is driven by anxiety over insufficient milk production, a concern that was echoed in 68.1% of the galactagogue users in our cohort. This anxiety often stems from the inability to directly breastfeed during NICU admission, compounded by infrequent pumping and delayed lactogenesis(7,8).

Importantly, our study reveals a strong association between SOS prescriptions and prolonged use. The vagueness of "as-needed" orders leaves interpretation to the mother, who may continue the drug out of fear or misinformation. Similar trends have been reported to emphasize the need for precision in galactagogue prescribing practices(9).

The continued use without medical consultation in nearly 29% of users is alarming. This self-medication highlights the lack of clarity in communication between healthcare providers and mothers, and possibly, a deficit in postpartum lactation counseling. Notably, 65.3% of galactagogue users expressed a desire for better information on when and how to stop. This demonstrates an unmet educational need that could be bridged by routine lactation counseling and clearer discharge instructions(10,11).

Another critical aspect is the psychological dimension. Perceived low milk supply, even in the absence of clinical indicators, was significantly associated with prolonged use. Maternal confidence plays a central role in successful lactation(12–14). Several studies, including have emphasized that interventions aiming to boost maternal self-efficacy in breastfeeding are more sustainable than pharmacological approaches alone(15–18).

Interestingly, demographic variables such as maternal age and education level did not significantly influence prolonged use. This suggests that even educated mothers, when emotionally overwhelmed, may resort to extended galactagogue intake if reassurance and support are lacking.

Our results advocate for a re-evaluation of current prescription practices in NICUs. Prescribing galactagogues with a clear end date and incorporating routine review sessions can mitigate overuse. Moreover, involving lactation consultants in NICU rounds could ensure ongoing support and assessment of actual milk output.

Strengthening early postpartum lactation education, particularly within 48 hours of delivery, may improve maternal understanding of normal lactation physiology and reduce premature dependence on supplements. Evidence-based guidelines should also consider incorporating structured weaning protocols for galactagogues, akin to tapering strategies used for other medications(1,19,20).

The use of standardized educational materials and post-discharge lactation hotlines may further empower mothers to manage lactation challenges appropriately(21–23). Future research could explore the effectiveness of such interventions in reducing unnecessary galactagogue use.

Limitation

Although follow-up was conducted until 52 weeks postmenstrual age, this study did not include systematic documentation of maternal or neonatal complications specifically related to galactagogue use. In particular, potential side effects or adverse outcomes of prolonged use were not consistently monitored or recorded. This limits

Vol. 19 (Supplementary Issue 4), Oct-Dec 2025, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2025.4s.28

our understanding of the safety and clinical implications of extended galactagogue intake. Future research should include structured, detailed monitoring to evaluate such outcomes comprehensively.

Conclusion

This study identifies significant gaps in the management of galactagogue use among mothers of preterm infants. The findings highlight that prolonged use is common, particularly among those who receive SOS prescriptions or perceive their milk supply as inadequate. The lack of clear prescribing guidance and discontinuation instructions contributes to unnecessary reliance on pharmacological support.Efforts to enhance lactation education, establish clear prescribing protocols, and improve communication between providers and mothers are essential. Incorporating lactation consultants in NICU care and reinforcing maternal confidence through early and ongoing counseling may reduce prolonged galactagogue use and improve breastfeeding outcomes.Addressing these gaps can support rational galactagogue use and promote sustained breastfeeding success among mothers of vulnerable neonates.

Acknowledgement

The authors acknowledge the support of the Department of Neonatology at Sri Ramachandra Institute of Higher Education and Research.

Conflicts of Interest

The authors declare thatno conflicts of interest.

References

1. Mcguire W, Henderson G, Fowlie PW. ABC of preterm birth Feeding the preterm infant; Available from: http://www.bmj.com/
2. World Health Organization. WHO recommendations for care of the preterm or low birth weight infant.Geneva: [Internet]. Geneva; 2022. Available from: https://apps.who.int/iris/bitstream/handle/10665/363697/9789240058262-eng.pdf
3. Khorana M, Wongsin P, Torbunsupachai R, Kanjanapattanakul W. Effect of Domperidone on Breast Milk Production in Mothers of Sick Neonates: A Randomized, Double-Blinded, Placebo-Controlled Trial. Breastfeed Med. 2021 Mar;16(3):245–50.
4. Grzeskowiak LE, Smithers LG, Amir LH, Grivell RM. Domperidone for increasing breast milk volume in mothers expressing breast milk for their preterm infants: a systematic review and meta-analysis. BJOG [Internet]. 2018 Oct 1;125(11):1371–8. Available from: https://pubmed.ncbi.nlm.nih.gov/29469929/
5. McBride GMK, Rumbold AR, Keir AK, Kunnel A, Buxton M, Jones S, et al. Longitudinal trends in domperidone dispensing to mothers of very preterm infants and its association with breast milk feeding at infant discharge: a retrospective study. BMJ Paediatr Open [Internet]. 2023 Nov 3; 7(1). Available from: https://pubmed.ncbi.nlm.nih.gov/37923344/
6. Dandotiya H, Singh G, Kashaw SK. The Galactagogues Use by Indian Tribal Communities to Over Come Poor Lactation. 2013;4(3):243–8.
7. Zizzo G, Rumbold AR, Grzeskowiak LE. “Fear of stopping” vs “wanting to get off the medication”: exploring women’s experiences of using domperidone as a galactagogue - a qualitative study. Int Breastfeed J [Internet]. 2021 Dec 1;16(1):1–13. Available from: https://internationalbreastfeedingjournal.biomedcentral.com/articles/10.1186/s13006-021-00438-5
8. McBride GM, Stevenson R, Zizzo G, Rumbold AR, Amir LH, Keir A, et al. Women’s experiences with using domperidone as a galactagogue to increase breast milk supply: an australian cross-sectional survey. Int Breastfeed J [Internet]. 2023 Dec 1; 18(1):1–9.
9. Bazzano AN, Littrell L, Brandt A, Thibeau S, Thriemer K, Theall KP. Health provider experiences with galactagogues to support breastfeeding: a cross-sectional survey. J Multidiscip Healthc [Internet]. 2016 Nov 17;9:623–30. Available from: https://www.dovepress.com/health-provider-

experiences-with-galactagogues-to-support-breastfeedin-peer-reviewed-fulltext-article-JMDH
10. Bazzano AN, Cenac L, Brandt AJ, Barnett J, Thibeau S, Theall KP. Maternal experiences with and sources of information on galactagogues to support lactation: A Cross-Sectional study. Int J Womens Health. 2017 Feb 27;9:105–13.
11. Tan ML, Foong SC, Foong WC, Ho JJ. Use of Galactagogues in a Multi-Ethnic Community in Southeast Asia: A Descriptive Study. Int J Womens Health [Internet]. 2022;14:1395–404. Available from: https://www.tandfonline.com/doi/pdf/10.2147/IJWH.S366288
12. He J, Yimyam S, Namprom N. Breastfeeding self-efficacy, social support, and breastfeeding among Chinese mothers with late preterm infants. Journal of Neonatal Nursing [Internet]. 2022;28(1):21–5. Available from: https://doi.org/10.1016/j.jnn.2021.07.005
13. Li F, Huang C, Lin Q, Xi Y, Xiang C, Yong C, et al. Maternal Characteristics, Intention, Self-Efficacy, Perceived Social Support, and Exclusive Breastfeeding Practice: Structural Equation Modeling Approaches. Healthcare 2023, Vol 11, Page 87 [Internet]. 2022 Dec 28;11(1):87. Available from: https://www.mdpi.com/2227-9032/11/1/87/htm
14. Ahmed AH, Rojjanasrirat W. Breastfeeding Outcomes, Self-Efficacy, and Satisfaction Among Low-Income Women With Late-Preterm, Early-Term, and Full-Term Infants. J Obstet Gynecol Neonatal Nurs [Internet]. 2021;50(5):583–96. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med19&NEWS=N&AN=34390676
15. Webber E, Wodwaski N, Courtney R. Using Simulation to Teach Breastfeeding Management Skills and Improve Breastfeeding Self-Efficacy. J Perinat Educ [Internet]. 2021 Jan 1;30(1):19. Available from: /pmc/articles/PMC7819477/
16. Otsuka K, Taguri M, Dennis CL, Wakutani K, Awano M, Yamaguchi T, et al. Effectiveness of a breastfeeding self-efficacy intervention: Do hospital practices make a difference? Matern Child Health J. 2014;18(1):296–306.
17. Gökçeoğlu E, Küçükoğlu S. The relationship between insufficient milk perception and breastfeeding self-efficacy among Turkish mothers. Glob Health Promot. 2017;24(4):53–61.
18. Rosenblad AK, Funkquist EL. Self-efficacy in breastfeeding predicts how mothers perceive their preterm infant's state-regulation. Int Breastfeed J [Internet]. 2022;17(1):44. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med22&NEWS=N&AN=35690825
19. WHO. Guideline: Counselling of Women to Improve Breastfeeding Practices [Internet]. 2018. 4–8 p. Available from: https://www.who.int/publications/i/item/9789241550468
20. Brodribb W. ABM Clinical Protocol #9: use of galactogogues in initiating or augmenting maternal milk production, second revision 2018. Breastfeed Med. 2018 Jun 1;13(5):307–14.
21. Aksu H, Küçük M, Düzgün G. The effect of postnatal breastfeeding education/support offered at home 3 days after delivery on breastfeeding duration and knowledge: a randomized trial. J Matern Fetal Neonatal Med. 2011 Feb;24(2):354–61.
22. Maycock B, Binns CW, Dhaliwal S, Tohotoa J, Hauck Y, Burns S, et al. Education and Support for Fathers Improves Breastfeeding Rates. Journal of Human Lactation [Internet]. 2013 Apr 19;29(4):484–90. Available from: https://journals.sagepub.com/doi/10.1177/0890334413484387?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed
23. Bennett CF, Galloway C, Grassley JS. Education for WIC Peer Counselors About Breastfeeding the Late Preterm Infant. J Nutr EducBehav [Internet]. 2018;50(2):198-202.e1. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med15&NEWS=N&AN=28818488