Original Article

Risk factors for infant formula usage during the initial hospital stay in term and late pre-term neonates after implementation of a breastfeeding support program: A retrospective case–control study from a tertiary care hospital

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ABSTRACT

Background: Infant formula usage in hospitals is inevitable in certain circumstances. We explored the high-risk groups who required formula during hospital stays during the post-intervention phase of a quality improvement initiative for improving exclusive breastfeeding (EBF) rates in hospitals. **Methods:** A retrospective and case–control study was conducted involving 50 cases of neonates who received infant formula and 200 control who were exclusively breastfed. Data regarding maternal and neonatal details were from breastfeeding assessment forms and case record which was collected prospectively during the program. We compared common risk factors between the two groups. **Results:** There was a strong association between infant formula usage and cesarean sections, assisted reproductive technology (ART) conceptions, multiple gestations, neonatal intensive care unit admissions, being small for gestational age, and being an infant of a diabetic mother. First-h breastfeeding was associated with a higher likelihood of EBF in the hospital. In the final model, ART conception, multiple gestations, and delayed initiation of breastfeeding were strong predictors of the use of infant formula in the hospital. **Conclusion:** Initiating breastfeeding within the 1st h promotes EBF. ART conception and multiple gestations remain strong risk factors for formula usage, the social, physiological, and genetic reasons for which will need to be studied in detail.

Key words: Breastfeeding, Case–control study, 1st –h breastfeeding, Formula feeding

In accordance with the World health organization and the UNICEF- Baby-Friendly Hospital Initiative (BFHI) guidelines, most organizations now advocate exclusive breastfeeding (EBF) till 6 months of age [1]. Many countries are still struggling to achieve an EBF rate of even 50% at 6 months of age [2]. The promotion of breastfeeding has become a world health priority. Early EBF in hospitals and supplementing infant formula only for medical indication is advocated by policy-makers [3], as research shows that EBF in hospitals is directly associated with higher EBF rates in the community in the first 3 months [4,5]. The number of hospitals that achieve EBF rates is very few with average in-hospital breastfeeding rates even in BFHI hospitals being 79.8% [6]. In contrast, there are also contradicting concerns of harm caused by inconsiderate stringent rules to promote EBF, particularly during the initial few days in the hospital [7]. Infant formula supplementation happens many times in the first 3 days when the mother-baby duo is in the hospital for medical reasons, lactation management issues, and personal choices [8]. Theoretically, early infant formula supplementation will interfere with the supply-demand process for lactogenesis [9]. From a physician's perspective, the risks to the neonates because of breastfeeding failure always take a higher priority when compared to supporting breastfeeding [10]. "Do no harm" is the dictum in modern healthcare. Post-BFHI era in developed countries has seen a marginal increase in neonatal intensive care unit (NICU) admissions and the need for intravenous fluids for neonatal hypoglycemia, due to the overzealous adherence to EBF in hospitals [11-13]. These conditions affect the long-term neurodevelopmental outcomes of babies, a very significant outcome that breastfeeding was supposed to protect.

Few issues resulting in nonEBF in a hospital setting can be addressed by close breastfeeding supervision and support by skilled lactation support staff which many hospitals lack currently. Data on the high-risk groups for infant formula usage in hospitals will help in enhancing breastfeeding support for this duo specifically.

In our tertiary care hospital, a breastfeeding support program called "Born and Begin" was initiated to improve in-hospital EBF rates. This quality improvement (QI) program conducted between August 2019 and February 2020 was closely adherent to the ten

Access this article online	
Received - 06 March 2023 Initial Review - 13 March 2023 Accepted - 19 March 2023	Quick Response code
DOI: 10.32677/ijch.v10i5.3910	

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steps of BFHI. At the end of 6-month post-intervention phase of the study the EBF rates were still 80–90% which was sustained for 2 years. The data obtained during the study were used to conduct a case–control analysis for risk factors for infant formula usage in hospitals in the post-intervention phase of the QI project.

METHODS

The QI program created and trained a team of breastfeeding counseling nurses who visited and assessed every mother and baby duo daily and formulated a feeding plan for the next 2 days.

Nurses were trained on early initiation of breastfeeding including after cesarean section and early expression of breastmilk. The Program also restricted infant formula usage to specific medical indications adapted from the Academy of Breastfeeding Medicine [3] (Table 1).

The data for this study was obtained from patient records and breastfeeding assessment forms where all breastfeeding-related data are entered. We used the "every feed basis" method of documenting infant formula usage. Here, the use of infant formula with volume was documented on a feed-to-feed basis by the nurses, which was confirmed with 24-h recall by the mother. EBF in the hospital was defined by a neonate who has not received a single feed with formula from birth till discharge from the hospital. With the existing EBF rates of 80% and statistical power of 0.8 and margin of error of 5% and considering a 1:4 ratio of cases: control, a sample size of 45 cases and 180 control were calculated by the Kleley method. We took 50 cases and 200 controls from inborn neonates born between August 2020 and February 2021. The neonates were more than 35 weeks of gestation and more than 1900 grams (the study population for the QI study). The cases were chosen consecutively from the hospital's birth register and two exclusively breastfed babies born before and two after the formula-fed baby were chosen as controls. All these babies were completely roomed in with mothers as per hospital policy unless there were additional comorbidities. All of them had daily weight checks until discharge. Blood sugar monitoring, testing for hyperbilirubinemia, and management of hypoglycemia were all as per standard protocols. Infant formula was provided only after the physician's order by the nurse. The parameters considered for comparison were maternal age, mode of conception, parity, mode of delivery, plurality, time of breastfeeding initiation, NICU admission, gestational diabetes mellitus, intrauterine growth status, and low birth weight. We did not include neonatal conditions such as hypoglycemia and weight loss in the model as they themselves are indications for infant formula supplementation. Chi-square analysis was used for comparing cases and controls and the final model was created using logistic regression.

Table 1: Indication for expressed breast milk and infant formula usage in hospital

Indications for infant formula feeding	Indications for expressed breast milk use
1. Hypoglycemia for immediate recovery (Blood sugar >35 mg/dL but <45 mg/dL) 2. Signs of inadequate lactation with danger signs a. Dehydration fever b. Oliguria c. Weight loss percentage crossing 75th centile 3. Mother too tired for breastfeeding or milk expression 4. Mother has decided on formula feeding 5. Mother not available	1. Adequate lactation but baby having poor latch or suck 2. Borderline sugars and baby not feeding well 3. Engorged maternal breasts 4. Baby and mother separated

RESULTS

The median gestational age was 38 weeks (IQR: 37–39 weeks), and the mean birth weight was 3016 (±435) g. The cesarean section rate was 67% and 68% of neonates were born to primiparous mothers. Pregnancies by assisted reproductive technology (ART) were around 20% (n=50). Despite a higher cesarean rate, 91% of neonates were breastfed in the 1st h of life. Of the 50 neonates who received infant formula during the hospital stay, 46% (n=23) received formula as per American academy of pediatrics (AAP) guidelines for hypoglycemia, 22% (n=11) as mothers requested infant formula because of lactation problems, 16% (n=8) as there was excessive weight loss or evidence of dehydration, 10% (n=5) as neonates were admitted in NICU, and 6% (n=3) as there were anomalies which interfered with breastfeeding.

There was a strong association between the use of infant formula milk and NICU admission (OR=9.7, 95% CI: 3.1–30), conception by ART (OR=7.9, 95% CI- 3.9–15), being one of the twins (OR=9.9, 95% CI- 4.0–24.4) and maternal age is more than 35 years (OR=6.0, 95% CI: 2.1–17.1). The other significant associations were being small for gestational age (OR=4.5, 95% CI: 1.6–12.8), being an infant of a diabetic mother (OR=3.0, 95% CI- 1.3–6.9), gestation <37 weeks (OR=4.4, 95% CI- 2.2–8.7), being low birth weight (OR=5.2, 95% CI-2.4–11.1), being born by a cesarean section (OR=5.5, 95% CI-2.2–14) (Table 2). There was a strong negative association between infant formula use and initiating breastfeeding within the 1st h (OR=0.14, 95% CI-0.05–0.3). In the final logistic analysis model, however, delayed initiation of breastfeeding beyond the 1st h, multiple pregnancies, and ART conception are significant predictors of using infant formula in the hospital.

DISCUSSION

Awareness of factors that impede EBF in hospitals is vital to improving breastfeeding rates and forms the basis for formulating hospital and national-level breastfeeding policies. We aimed to improve on the existing knowledge base and elucidate important information about the risks of formula feeding in hospitals with a well-oiled lactation support system and a high baseline breastfeeding rate. In this study, medical reasons for formula feeding accounted for more than half of the cases and modifiable risk factors for formula use were a minority which in itself is a

Table 2: Comparison of parameters between cases and controls

Parameters	Cases	Control	OR for use of infant formula (95% CI)
Weight in grams±SD OR For <2500 g	2816±434	3070±404	5.2 (2.4–11.1)
Gestation in median weeks for <37 weeks	37 (IQR: 36–38) weeks	38 (IQR: 37–39) weeks	4.4 (2.2–8.7)
Primiparous mother	78%	64.5%	1.8 (0.9–3.8)
Mode of delivery being cesarean	96%	60.5%	5.5 (2.2–14)
1st h breastfeeding	78%	95%	0.14 (0.05–0.3)
Fetal growth status*			
SGA[a]	18%	3.5%	4.5 (1.6–12.8)
LGA[b]	2%	1.5%	1.3 (0.14–13.1)
AGA[c]	80%	95%	Reference
Maternal age			
<20 years	0%	0.5%	Cannot be estimated.
21–35 years	80%	96.5%	Reference
>35 years	20%	3%	6.0 (2.1–17.1)
NICU stay	20%	2.5%	9.7 (3.3–30)
Gestational diabetes mellitus in mother	24%	8%	3.0 (1.3–6.9)
ART conception	52%	12%	7.9 (3.9–15)
Multiple gestations	16%	4.5%	9.9 (4–24.4)

***Defined by the WHO-Fenton's growth chart 2013, [a]SGA: Small for gestational age; weight <10th centile for gestational age, [b]AGA: Appropriate gestational age, [c]LGA- weight >90th centile for gestational age**

testimony to the effect of the lactation support system in place in the institution.

Unsurprisingly, we found the odds of use of formula feeding highest in mothers with ART conception (OR=7.9, 95% CI: 3.9–15), being one of the twins (OR=9.9, 95% CI: 4–24.4), advanced maternal age (OR=6, 95% CI: 2.1–17.1). The association between the use of formula and NICU admission was also very strong (OR=9.7, 95% CI: 3.1–30). Frequently, all these risk factors exist in the same mother-baby dyad thereby increasing the risk of formula feeding manifold.

Existing evidence of the potential impact of ART on breastfeeding is inconclusive. A large retrospective study done by Barrera *et al*., based on maternal reported data, has shown that even though the intention to breastfeed and initiation of breastfeeding does not differ according to the mode of conception [14]. ART conception is a risk factor for early cessation of breastfeeding. Pregnancies through ART tend to be associated with higher maternal age, multiple gestations, multiple comorbidities, NICU admissions, and pre-term delivery. It causes for difficulty in breastfeeding in the previous studies range from low milk supply, perception of inadequate milk, and neonatal admission to NICU. The difference existed even when antenatal education and postnatal lactation support was adequate.

On contrary, in a retrospective cohort study from Taiwan [15], the effects of the mode of conception on breastfeeding outcomes became not significant in cases of singleton birth. In a Swiss cross-sectional study of mothers of singletons conceived by ART, there was no difference in breastfeeding initiation or duration when compared to a population control group [16]. These studies suggested that to further increase EBF rates in ART conception is to increase single embryo transfer as opposed to the more prevalent practice of multiple embryo transfer. In our population of 26 babies born out of twins, pregnancy 16 was due to ART conception. In our final logistic regression model too, multiple pregnancies and ART conception are the significant predictors of using infant formula in the hospital. Conception through ART is also associated with the feeling of guilt associated with the pressure to exclusively breastfeed. Knowledge and awareness that there is a greater chance of breastfeeding failure in this group of mother-baby dyads can help in preventing undue stress and psychological effects on the mother in an already vulnerable period. Mother-baby duo with multiple pregnancies and ART conception will need additional support and strong breastfeeding support from the beginning as they are at high risk for requiring infant formula in the hospital [17].

This study once again brings out the importance of 1st-h breastfeeding. Although all parameters when tested independently showed a negative or positive association with breastfeeding, in the final model, 1st-h breastfeeding showed the highest association with EBF in the hospital. There have been many studies previously proving the association of 1st-h breastfeeding with prolonged breastfeeding as long as 3 months postpartum [18,19]. The association might be because of known physiological reasons where the separation of the placenta causes a fall in progesterone which if coincides with the baby's suckling will cause maximal prolactin secretion [6,20]. Furthermore, based on the new prolactin receptor theory, removal of colostrum within the 1st h enhances response to prolactin peaks by increasing the number of prolactin receptors in the breast tissue [21]. This delay in the initial breastfeeding beyond 1 h might exhibit excessive weight loss, or perceived milk insufficiency in the 2nd or 3rd days resulting in formula supplementation.

Neonatal admissions to NICU are another major factor interfering with the successful establishment of breastfeeding both in the ART and spontaneously conceived mother-baby group. Streamlining neonatal admissions and avoidance of well late preterm admissions to NICU is another intervention that could help in improving the success of breastfeeding in this population.

In our institution, well late pre-term neonates are roomed in with the mother under close supervision and separation is avoided.

The results of our study are similar to the large multicenter survey done in CDC-governed hospitals, where medical indications contributed maximally to the use of infant formula in hospitals [8,11]. Low blood sugars contributed to half of the cases who received infant formula – a situation that cannot wait for lactation management. The other common indication for supplementation in our study was excessive weight loss. Retrospective assessments in the post-BFHI era in many centers also showed an increase in neonatal admissions to NICU for hypoglycemia and the need for intravenous fluids for hypoglycemia, which was later controlled by the implementation of the AAP hypoglycemia management bundle [11,22]. Our study and the previous works prove that infant formula supplementation is inevitable for such babies despite providing maximal breastfeeding support.

Perceived Insufficient Milk Supply or PIMS is the mother's belief that her milk is insufficient in quantity or quality for her baby. PIMS is reported as the most common reason for infant formula supplementation [23]. On contrary, our study contributed to only one-fourth of the cases because of the stringent rules for use of the formula. PIMS is high in centers with high cesarean rates, a higher proportion of ART, and multiple gestations. This group is amenable to antenatal and postnatal breastfeeding support and counseling.

The study also showed associations between cesarean section, gestational diabetes mellitus, and infant formula usage. However, these parameters did not stand significant in the logistic regression model. We have tested only commonly perceived factors affecting EBF. A larger study testing all maternal and neonatal factors might bring out the independent importance of many more peripartum factors affecting EBF. Further, this study poses a small risk of reporting bias as we collected cases and control only where records were complete – that is, the lactation counseling team has assessed completely and documented all details.

The limitation of our study is that we did not include preterm and Outborn neonates and did not score the breastfeeding efficiency. Furthermore, causes for infant formula supplementation are usually multifactorial (e.g., A mother might be demanding formula as her newborn is losing weight) and it cannot be oversimplified for a single reason. Infant formula supplementation should be provided when required for all medical indications. The strengths of our study are that infant formula usage was documented on an "every feed basis" which negates any false reporting of EBF [24]. As formula usage due to family requests was less, the study revolves more around legitimate indications for infant formula usage in hospitals.

CONCLUSION

This study brings out the risk factors for using infant formula in hospitals in a well-controlled setup. Rather than restricting formula use in hospitals, the focus should be the facilitation of normal lactation with early initiation of breastfeeding and counseling. Establishing the ten steps of BFHI should be treaded carefully against the dreads of complications due to lactation failure. A clear understanding of risk factors where EBF might not be possible will help in providing extra support to these mothers and prevent delays in supplementation when medically indicated. The purpose should be to create a hospital environment that is conducive to successful breastfeeding by offering optimal care and opportunities for mother-infant bonding. The future studies should focus on the genetic, physiological, and biochemical factors of human milk production in the high-risk groups.

AUTHORS CONTRIBUTION

- Suja Mariam G (SM): Devised the study and collected the data wrote first draftand approved the final manuscript as submitted
- Siddartha Buddhavarapu (SB): Approved the study design, supervised data collection, revised, and approved the final manuscript as submitted.

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Funding: None; Conflicts of Interest: None Stated.

How to cite this article: Mariam S, Buddhavarapu S. Risk factors for infant formula usage during the initial hospital stay in term and late pre-term neonates after implementation of a breastfeeding support programme: A retrospective case–control study from a tertiary care hospital. Indian J Child Health. 2023; 10(5):60-64.