Lithium use during breastfeeding was safe in healthy full-term infants under strict monitoring

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Abstract

Aim: Previous studies on breastfeeding during lithium therapy have shown conflicting results. The aim of this study was to evaluate the safety when practising thorough follow-up of the infants.

Method: This retrospective study focused on women with lithium medication, and their breastfed infants born between 2006 and 2021 in Stockholm, Sweden. Information about infant serum lithium concentrations and clinical status was collected from medical records.

Results: In total, 30 infants exposed to lithium through breastmilk, 21 girls and 9 boys, were included. The median age at follow-up was 40 days (range 8–364 days). The median lithium serum concentration was 0.10 mmol/L in the second week of life (range <0.05–0.7 mmol/L), 0.08 in week 2–4 (range <0.05–1.2), 0.06 in the second month of life (range <0.05–0.2) and 0.07 after 2 months of age (range <0.05–0.2). Unexpectedly high lithium concentrations were found in two infants in the first month of life. Apart from poor weight gain, no adverse effects were found.

Conclusion: Serum lithium concentrations in breastfed infants were stabilised at barely measurable levels after the first weeks of life. Before that, concentrations higher than the mothers were found. Lithium treatment during breastfeeding can be considered safe under strict follow-up.

Keywords: bipolar disorder, breastfed infants, drug concentrations, lactation, Lithium

1 | INTRODUCTION

Bipolar disorder affects women of childbearing age and is most commonly treated with lithium. Discontinuing the treatment during pregnancy and lactation is sometimes an option but may imply serious risks to both mother and child due to the high risk of maternal relapse.\textsuperscript{1,2} Lithium passes freely over the placenta, and at the time of the delivery, the lithium concentrations are equilibrated in maternal and infant sera. Previous studies have shown an association between lithium treatment during pregnancy and cardiac malformations, but the absolute risks are low.\textsuperscript{1,3,4} The neonatal morbidity after intrauterine exposure to lithium includes drowsiness, decreased muscle...
We hypothesised that most infants were not affected by the maternal lithium treatment with the current clinical regime in Stockholm, or during polypharmacy.

Breastfeeding has traditionally been discouraged during lithium treatment due to two cases of high infant serum lithium concentrations during breastfeeding in the 1970s, caused by infant dehydration and maternal diuretic therapy in pregnancy. However, breastfeeding is highly encouraged in Sweden, and around 85% of the children are breastfed at 2 months of age. Many women with bipolar disorder who are clinically stable due to lithium treatment wish to breastfeed their infants unless there is a clear contraindication. Furthermore, breastfeeding is known to reduce stress and anxiety in the mother and is associated with a decreased risk for postpartum depression. It has also been associated with enhanced attachment and positive neurodevelopmental outcomes in the infant. Consequently, there is an uncertainty about whether abstaining from breastfeeding is the best choice for the mother and child, or if the positive effects could override the negative.

Previous case series and reports include a total of 40 mother-infant dyads. The lithium concentrations in breastmilk are reported to be around 12%–46% and in infant serum around 20%–50% of the maternal serum concentration. There are no larger studies available, where the effects in infants exposed to lithium via breastmilk are described. Furthermore, no studies have evaluated the safety of breastfeeding when the infant is enrolled in a structured follow-up programme, or during polypharmacy.

The aim of this study was to evaluate the safety of breastfeeding during lithium therapy with the current clinical regime in Stockholm. We hypothesised that most infants were not affected by the maternal treatment, but that the follow-up was necessary to identify infants who needed special attention.

2 | PATIENTS AND METHODS

2.1 | Study design

This was a retrospective cohort study on mothers treated with lithium and their breastfed infants. Information about maternal treatment, maternal and infant serum lithium concentrations and infant clinical status was collected from the electronic patient files. The main outcomes were the serum lithium concentrations in the infants and the ratio between the infant and the maternal serum lithium concentrations. The secondary outcomes were infant growth, recommendations to reduce breastfeeding, infant kidney and thyroid function and other reported adverse events. The study was approved by the Swedish Ethical Review Authority (dnr 2020–05558).

2.2 | Subjects

The study cohort was identified through diagnostic codes in the medical records. The infants were followed up at the Neonatal and Liljeholmen Paediatric Outpatient Clinics at Karolinska University Hospital and at the Neonatal Outpatient Clinic at Sachs’ Children’s and Adolescents’ Hospital at Southern Hospital, Stockholm, Sweden. The follow-up period ranged from January 2018 to June 2021 at Karolinska and, from January 2006 to June 2021 at Sachs’ Children’s Hospital. The parents were given a complete description of the study and asked for consent to participate by mail and telephone. Written informed consent was acquired for 30 infant-mother dyads.

2.3 | Clinical follow-up

This was a retrospective study, and the infant-mother pairs were followed as per the clinical follow-up routine at the time of their inclusion. According to the routine established at Karolinska University Hospital in 2018, the maternal lithium dose was titrated by the psychiatrist. If the mother-to-be and her psychiatrist felt that breastfeeding was feasible, the mother was referred to an experienced paediatrician antenatally. The paediatrician provided the mother with information about potential risks for the infant, and of the structure of the follow-up routine. At the time of delivery, the infant serum lithium concentration was measured in the umbilical cord. In conjunction with the metabolic screening at 48 h of age, tests for thyroid and kidney function were analysed as well as a second serum lithium concentration. The results were assessed by a paediatrician before the infant was discharged. Subsequently, follow-up visits at 2, 4 and 8 weeks of age were performed. They included infant serum lithium concentrations, tests for thyroid and kidney function and clinical examination. After 8 weeks, clinical follow-up was continued only if deemed necessary.

The clinical examination included a routine infant physical examination, weight measurement and questions regarding sleep, feeding and the general well-being of the infant. Throughout the follow-up, the mothers were instructed to stop breastfeeding and contact the health care in case of dehydration or signs of lithium intoxication of the infant. At Sachs’ Children’s and Adolescents’ Hospital, the follow-up was similar, but performed at less structured time intervals.

2.4 | Data collection

The data were collected from medical records. Information on maternal illness, smoking, use of alcohol, social factors and

Key Notes

- Previous studies on breastfeeding during lithium therapy have shown conflicting results.
- After 1 month of age, the infant serum lithium concentrations were barely detectable, but before that, the concentrations could be higher and poor weight gain was seen in some infants.
- Lithium treatment during breastfeeding can be considered safe under strict follow-up.
pharmacotherapy during pregnancy and breastfeeding, including the maternal dose of lithium and her serum lithium concentrations, was collected from the mothers’ healthcare records. The infants’ serum lithium concentrations during breastfeeding, their growth, morbidity and diagnoses, their level of breastfeeding and the concentrations of thyroid-stimulating hormone, thyroid hormone, sodium, potassium and creatinine were collected from the infants’ healthcare records.

All serum lithium concentrations were analysed by a colorimetric method, Modular P (2006 to 2016) or the Cobas 8000 c502 (2016 and later, both by Roche, Basel, Switzerland). The Karolinska University Laboratory has made a comparison of the instruments and demonstrated a good level of concordance. The estimated uncertainty of measurement was 10% for concentrations around 0.5 mmol/L and 5% for concentrations around 1.4 mmol/L. The infant serum lithium concentrations were not considered to represent trough levels. The maternal concentrations were assumed to be trough concentrations, since that is according to the clinical routine. Furthermore, maternal concentrations were measured in the early morning. However, the individual information was not available in our data.

All mothers were presumed to be in steady-state, as no dose changes had been made in the week before their serum lithium concentrations were measured.\textsuperscript{21}

2.5 | Data analysis

The follow-up visits were grouped based on the postnatal age at the visit: within 2 weeks of age, between 2 and 4 weeks of age, between 1 and 2 months of age and over 2 months of age.

We found that 27 women were treated with lithium sulphate, and three women were treated with lithium carbonate. A tablet of 42 mg lithium sulphate equals three quarters of a 300 mg tablet of lithium carbonate as to level of active substance.\textsuperscript{22–24}

The detection limit of lithium in serum was 0.05 mmol/L. For cases with undetectable lithium concentrations, the value 0.049 was used in calculations. This was chosen in order to not underestimate the effect of the drug exposure. To calculate the infant–mother ratio, the maternal concentration closest in time to the infant’s was used. A sub-analysis was performed for the 11 mother–infant dyads where the maternal serum lithium concentration was accepted if the maternal dose was unchanged, and the mother was considered to have stable serum lithium levels. A total of 43 infants exposed to lithium during breastfeeding were identified through diagnostic codes in the medical records. Of these, 11 were followed at Karolinska University Hospital and 32 at the Sachs’ Children’s and Adolescents’ Hospital. The parents of 13 infants were unreachable, refused participation or agreed to participate but never returned the consent forms. The analysed cohort consisted of 30 infant–mother pairs, nine from Karolinska University Hospital and 21 from Sachs Children’s and Adolescent’s hospital. Two pairs of siblings were included, but no twins. All but three infants were also exposed to lithium during pregnancy. The included infants attended to a total of 71 follow-up visits: 16 infants to three visits, nine infants to two visits and five infants were followed up once. Out of the visits, eight were performed before 2 weeks of age, 18 between 2 weeks and 1 month of age, 26 between 1 and 2 months of age and 19 after 2 months of age.

2.6 | Statistical analysis

Outcome data were tested for normal distribution. Continuous data were presented as medians, means, SD and ranges as per distribution and categorical variables as percentages. Related samples Wilcoxon signed rank test was used for comparison of concentrations measured before and after 1 month of age. p-values <0.05 were considered statistically significant. The statistical analyses were conducted by using SPSS version 28 (IBM Corporation).

3 | RESULTS

A total of 43 infants exposed to lithium during breastfeeding were identified through diagnostic codes in the medical records. Of these, 11 were followed at Karolinska University Hospital and 32 at the Sachs’ Children’s and Adolescents’ Hospital. The parents of 13 infants were unreachable, refused participation or agreed to participate but never returned the consent forms. The analysed cohort consisted of 30 infant–mother pairs, nine from Karolinska University Hospital and 21 from Sachs Children’s and Adolescent’s hospital. Two pairs of siblings were included, but no twins. All but three infants were also exposed to lithium during pregnancy. The included infants attended to a total of 71 follow-up visits: 16 infants to three visits, nine infants to two visits and five infants were followed up once. Out of the visits, eight were performed before 2 weeks of age, 18 between 2 weeks and 1 month of age, 26 between 1 and 2 months of age and 19 after 2 months of age.

3.1 | Infant characteristics

Of the infants, 27 were born at term, whereas three were born late preterm at 35 + 2, 36 + 5 and 36 + 5 weeks of gestation. The mean (SD) birth weight was 3578 g (447 g) (Table 1). Two infants were large for gestational age, and the rest were appropriate for gestational age at birth. Half of the infants were exclusively breastfed (Table 2).

3.2 | Maternal characteristics

All but four mothers were diagnosed with bipolar disorder, 15 of them with type 1. Out of the women without bipolar disorder, three had experienced previous and/or current postpartum psychosis and one was prescribed lithium for other psychiatric conditions (Table 1). The maternal doses of lithium sulphate ranged between 21 and 336 mg, corresponding to 112–1800 mg of lithium carbonate. The maternal doses were largely unchanged throughout the follow-up (Table 2).

Of the women, 18 (67%) were treated with at least one additional psychotropic drug during breastfeeding. The most common psychotropic co-medications were antipsychotics (n = 7), antidepressants (n = 6), anxiolytics and sedatives (n = 10) and psychostimulants (n = 4). Half of the mothers had consumed alcohol 3 months before the
pregnancy and one third were smokers. None of the women reported alcohol intake after they found out that they were pregnant. Only 7% reported that they were smoking cigarettes at the time of admission to maternity care, and no illicit drug use was reported (Table 1).

### 3.3 Lithium concentrations in infant and maternal serum

The infant serum lithium concentrations were measured at 66 visits. The median infant serum lithium concentration was 0.07 mmol/L. The infant lithium concentrations decreased with postnatal age, and the concentrations measured before 1 month of age were significantly higher than the ones measured after 1 month of age, \( p = 0.036 \) (Table 3, Figure 2).

It was possible to relate 33 of the infant concentrations to a maternal serum lithium concentration. The median maternal lithium concentration was 0.6 mmol/L, and the intra-individual variation in the maternal concentrations was low. The mean infant-mother ratio was highest at 1–2 weeks of age (0.37) and decreased with time (Figure 1, Table S1a). The sub-analysis of 11 infant-mother ratios where the infant and maternal concentrations were measured within (Table 2).
24 h from each other did not differ from the ratios in the whole cohort (Table S1b).

### 3.4 | Adverse events

No infants developed any severe adverse events. All the plasma sodium ($n = 59$), plasma potassium ($n = 43$), plasma creatinine ($n = 58$), serum thyroid-stimulating hormone ($n = 60$) and serum thyroid hormone ($n = 27$) levels were within normal range. There was one exception with a sodium and one with a potassium level that was $0.1 \text{mmol/L}$ outside of the normal range, without any clinical significance. No infants were described as irritable and all had a normal muscle tone. Approximately 25% of the infants had inadequate growth during their first month of life (Table 3). Four mothers were advised to reduce breastfeeding and to increase the amount of formula given. The reasons for this were poor infant growth ($n = 1$), polypharmacy ($n = 1$) and elevated serum lithium concentrations in the infants ($n = 2$). Two infants were described as tired at their first outpatient visits. One of them also had poor weight gain and hyperbilirubinemia at 9 days of age, but their serum lithium concentration was only $0.2 \text{mmol/L}$. One week later, the baby was healthy and growing well.

### 3.5 | Cases of elevated lithium levels

Two infants had elevated serum lithium concentrations (Figure 2). One infant, born at 35 + 2 weeks of gestation, had a serum lithium concentration of 0.7 mmol/L at the first follow-up visit at 12 days of age. The level was 17% higher than the maternal concentration. The lithium concentrations in the umbilical cord and at 2 days of age were 0.9 and 0.6 mmol/L, respectively, and the infant had been admitted to neonatal care for a day due to a respiratory disorder. The infant’s weight was still below birth weight at the time of the visit. However, the infant was not assessed as tired or hypotonic and the general health was considered good. The infant had received formula from start and was breastfed around 75% at the time. The mother was recommended to reduce breastfeeding to around 50%, and 4 days later, the infant’s lithium concentration was below detection level.

Another infant reached a concentration of 1.2 mmol/L at the first follow-up visit at 29 days of age. Unfortunately, the maternal concentration was not measured. This infant had a normal growth and had no feeding problems at the time. The infant had however been observed at the neonatal ward after an apparent life-threatening event at 2 days of age at the postnatal ward. The infant’s lithium concentrations at birth were 0.9 mmol/L in the umbilical cord and 0.7 mmol/L in serum at the time of the event. The infant was partly breastfed both at the time of the event and at the polyclinical control. The mother was recommended to stop breastfeeding completely, and the follow-up was discontinued. No clinical complications to this border-line toxic concentration were documented in the infant’s chart.
DISCUSSION

This study of 30 breastfed infants and their mothers treated with lithium was the first to evaluate a clinical monitoring routine of lithium exposure through breastmilk. No severe adverse events were identified in any of the infants. The infants’ lithium levels decreased and stabilised at levels under 0.2 mmol/L after the first month of life, regardless of maternal lithium dose. Two infants with lithium concentrations within the therapeutic interval were identified. Both infants were clinically well, and the lithium concentration decreased within days after reduction in breastfeeding in the infant whose concentration was followed up. The mothers to these infants were treated with regular doses of lithium and were not treated with any other drugs causing drug–drug interactions with lithium. One of these infants was however born at 35 weeks of gestation. For the other, the recommended maternal lithium dose reduction after delivery was never carried out.

One of the strengths of this study was that it evaluated infants in a clinical setting, exposed to several psychotropic drugs as well as lithium. However, only psychologically stable and highly motivated women were included. Therefore, the results are only generalisable to other similar patients and not to all women treated with lithium. A limitation of the study design was the lack of a non-breastfed control group of infants exposed to lithium in utero to evaluate the un-specific clinical outcomes like poor weight gain and tiredness. These symptoms are common in new-borns, especially in infants exposed to lithium in utero.

There were some limitations regarding the laboratory analyses of serum lithium concentrations. The infant lithium concentrations were not documented to be trough concentrations, and the maternal serum lithium concentrations were not measured simultaneously with the infants’. However, the lithium concentrations in infant serum after exposure through breastmilk could be considered as relatively stable, related to an infant’s frequent feeding pattern and the documented long half-life of lithium, around 96 h, in new-borns. Furthermore, the maternal lithium doses were documented to be unaltered for at least 7 days before the sampling time. As the elimination half-life of lithium in adults is around 20 h, the maternal serum lithium concentrations were considered to be at steady state, with low inter-dose variation. This assumption is further supported by...
the results from the sub-analysis of the infant–mother ratios of the dyads in which the maternal concentration was taken in conjunction with the infant’s. Since these ratios were no different from the whole cohort, we conclude that the ratios can be generalised to all infants exposed to lithium through breastmilk.

Previous studies on infants exposed to lithium through breastmilk have been small, and their concentration measurements were performed later in life. The lower infant age at follow-up in this and one previous study may explain the higher infant serum concentrations. Furthermore, a polypharmacy effect on the clinical symptoms in the infants in this study could not be excluded. The women were not treated with drugs that would interact with the lithium elimination, such as diuretics. However, the clinical effects of lithium exposure, especially within the first month of life, were impossible to disentangle from the effects seen after foetal exposure to other psychotropic drugs.

The elevated serum lithium concentrations before 1 month of age might be explained by younger infants being more sensitive to dehydration and having a more immature kidney function. The concentrations measured before 10 days of age could also reflect the foetal lithium exposure, given the infant lithium elimination half-life of several days. After 1 month of age, all serum lithium concentrations were below 0.3 mmol/L, and infant growth was generally within normal range. This provides some support for the previous recommendation of discontinuation of the laboratory follow-up when lithium serum concentrations decrease to below 0.3 mmol/L.

More research will be needed to explain why some infants present with higher serum lithium concentrations than others. Furthermore, it is not clear if it is safe to breastfeed a late preterm infant, when the mother is treated with lithium. The lower kidney maturation and the increased risk of dehydration in preterm infants are considerable risk factors for lithium intoxication. The clinical guidelines at Karolinska University Hospital restrict breastfeeding during maternal lithium therapy to only full-term infants. They also recommend against exclusive breastfeeding but recommend introducing the bottle, at least once per day, to all exposed infants. This regimen provides the opportunity to quickly switch feeding strategy in case of dehydration or suspected lithium toxicity. We conclude that these limitations are supported by our results, but further studies are needed. Studies have not shown any negative neurodevelopmental effects after foetal exposure to lithium, but the long-term effects after postnatal lithium exposure are to our knowledge unstudied.

5 | CONCLUSION

Breastfeeding during treatment with lithium can be considered safe in healthy, full-term infants. However, repeated monitoring to identify the infants with unexpectedly high concentrations and with clinical symptoms is necessary. The first check-up should be no later than at 2–3 weeks of age.

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CONFLICT OF INTEREST

The authors report no financial relationships with commercial interests.

DATA AVAILABILITY STATEMENT

An anonymised dataset is available from the corresponding author on request.

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