Balancing Mental Health and Breastfeeding:

Evaluating the Transfer of Lurasidone Into Human Milk

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Abstract

Objective: Lurasidone, a second-generation atypical antipsychotic, lacks significant published data on its transfer into human milk during lactation. The objective of this study was to (1) quantify the transfer of lurasidone into human milk, allowing for an estimation of maternal drug exposure to the breastfed infant and (2) report observations of infants exposed to lurasidone via breast milk.

Methods: Milk samples and health histories were collected from 9 lactating mothers who donated milk samples to the InfantRisk Human Milk Biorepository while taking lurasidone (20–80 mg/day) from 2022 to 2024. The drug concentration-time profile of lurasidone in milk was determined using liquid chromatography–mass spectrometry, and maternal lurasidone doses were standardized to 40 mg/day.

Results: Lurasidone had an average milk concentration of 39.5 ng/mL at the 40 mg/day standardized dose. The relative infant dose (RID) was 1.16%, which is below the standard 10% threshold for infant safety. Even using the highest observed individual concentration of 174 ng/mL, the calculated RID was 3.03%. There were no maternal reports of adverse effects in the infants exposed to varying degrees of lurasidone in milk.

Conclusion: The levels of lurasidone observed in all participants' milk samples were exceedingly low. The subsequently low RID is below the 10% threshold for infant safety, suggesting that the transfer of maternal lurasidone into human milk is clinically insignificant and poses minimal risk to a breastfed infant.

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Bipolar spectrum disorders have an estimated 12-month prevalence of 1.5% and a lifetime prevalence of 2.4% based on an international health survey.[1] In women without a prior psychiatric illness, the prevalence of bipolar disorder is estimated to be around 2.6% in the perinatal period.[2] Of the 2.6% without a prior diagnosis of any psychiatric disorder, 20.1% experience a bipolar mood disorder during pregnancy and postpartum. This review also identified that 54.9% of women previously diagnosed with bipolar disorder experience at least 1 depressed, hypomanic, or mixed bipolar episode during the perinatal period.[2] Medication selection in the perinatal period for bipolar disorder can be affected by lactation status and concerns for fetal drug exposure from maternal medication use.[3] Patients and providers alike struggle with making risk-benefit decisions with second-generation antipsychotics, also called atypical antipsychotics, since they have not been widely studied in breastfeeding to date. Based on survey findings with other medications, it has been identified that providers may recommend breastfeeding abstinence even when the medication is not associated with known infant harm.[4]

Atypical antipsychotic use in the prenatal period, based on a US health plan analysis from 2001 to 2007, increased 2.5-fold compared to typical antipsychotics.[5] It was also noted in this analysis that a higher percentage of participants received atypical antipsychotics (0.72%) compared to typical antipsychotics (0.09%).[5] Pregnant women appear more likely to discontinue antipsychotic medications compared to nonpregnant women. According to a cohort study, only 19% of pregnant participants maintained their typical antipsychotic regimen by the third trimester, while only 38% continued their atypical antipsychotic medication.[6] Some information suggests that a lower percentage of patients on atypical antipsychotics had ever breastfed (59.3%) compared to a control group (88.2%).[7] A lower percentage of women on these medications also exclusively breastfeed at 3 months compared to the control group (23% vs 47%).[7]

Editor's Note
We encourage authors to submit papers for consideration as a part of our Focus on Women's Mental Health section. Please contact Marlene P. Freeman, MD, at psychiatrist.com/contact/freeman.

Clinical Points

- Untreated mood disorders in the peripartum period are associated with increased risks, including bipolar recurrence and obstetric complications.
- Lurasidone has a relative infant dose (1.16%) well below 10% safety standards, indicating that maternal lurasidone use while lactating is unlikely to cause harm to the breastfed infant.
- Lurasidone has an attractive safety and metabolic profile, there are no strong reports or indicators of infant harm noted, and it does not appear to impact milk production.

Several issues can develop in women with bipolar disorder who discontinue treatment with mood stabilizers in the perinatal period. A prospective observational cohort study including pregnant women diagnosed with bipolar type 1 and bipolar type 2 disorders identified that the bipolar recurrence risk was 71%.[8] Also among those who discontinued treatment, there was a 2-fold greater risk of bipolar recurrence, time to first recurrence was 4-fold shorter, and the proportion of weeks ill during pregnancy was 5 times greater.[8] The risk of bipolar disorder recurrence is concerning during pregnancy. There are also concerns for increased risk of obstetric complications in women diagnosed and treated for bipolar disorder as well. In an evaluation of pregnant women with bipolar type 1 (82%) or bipolar type II (18%), there was a 2-fold higher likelihood of cesarean section, 5.53-fold higher likelihood of preeclampsia, 4.13-fold higher likelihood of gestational diabetes, 3.53-fold higher likelihood of somatic illness with treatment, and 3.94-fold higher likelihood of somatic illness without treatment.[9] This study focused more on bipolar disorders and complications, without emphasis on how medication compliance or other factors might improve or worsen bipolar disorder outcomes. Though these observations result from studies on pregnancy, it is likely the patterns extend into the "fourth" trimester during peak periods of sleep disruption.

The rationale for antipsychotic discontinuation is not often elucidated but is surprising given that American College of Obstetricians and Gynecologists (ACOG) guideline on the treatment and management of mental health conditions during pregnancy and postpartum recommends against discontinuing mood stabilizers except for valproate due to risk of recurrence or exacerbation of mood symptoms and congenital malformations (strong-recommendation, moderate-quality evidence).[10] These guidelines recommend that patients who are stable while taking antipsychotic medications in the peripartum period should continue medications instead of switching to a different medication.

Lurasidone is an atypical antipsychotic approved by the US Food and Drug Administration (FDA) for schizophrenia and depressive episodes associated with bipolar I disorder as monotherapy or as adjunctive therapy with lithium or valproate.[11] Other available treatment options approved for bipolar depression include cariprazine, lumateperone, quetiapine, and olanzapine combined with fluoxetine. Lurasidone is not FDA-approved for managing acute bipolar mania or hypomania.

The drug activity of lurasidone is primarily attributed to the parent compound, which works by inhibiting dopamine type 2 receptors (D_2) and serotonin type 2 receptors.[11] It is well-documented that dopamine antagonism activity can result in increased prolactin levels and may impact lactation. Some information suggests that lurasidone increases prolactin levels to a lesser extent than risperidone.[12] A case report supported resolution of hyperprolactinemia when switching a patient from risperidone to low-dose lurasidone with appropriate titration.[13]

During the FDA approval process, human lactation studies were neither required nor conducted to assess the presence of lurasidone in human milk, its effects on breastfed infants, or its impact on milk production. Lurasidone is expected to have limited entry into human milk due to extensive first-pass metabolism through cytochrome P450 3A4 (CYP3A4). Furthermore, it has low oral bioavailability (9%–19%), high protein binding (>99%), and a large volume of distribution, all of which hinder the transfer of the drug across membranes.[11] A single case report in a mother exclusively breastfeeding on 80 mg of lurasidone observed a relative infant dose (RID) of 0.29% without signs of infant toxicity at day 39.[14] Lurasidone serum concentrations appear to fluctuate in the peripartum period based on a case report of 1 patient in whom lurasidone serum concentrations decreased during pregnancy but increased postpartum.[15] To date, limited data exist evaluating maternal lurasidone use and excretion into human milk. This study investigates the risk to the breastfed infant with maternal lurasidone use by examining the milk and infant outcomes of 9 women taking lurasidone at dosages ranging from 20 to 80 mg daily.

OBJECTIVE AND METHODS

The InfantRisk Human Milk Biorepository (HMB), Texas Tech University Health Sciences Center Amarillo (institutional review board [IRB] # A21-4214), provided the deidentified materials for this investigation. Electronic consent was obtained from the HMB participants. The HMB collects observational milk samples with various exposures of interest from lactating volunteers asynchronously. The samples are accompanied

by questionnaires with self-reported histories for the breastfeeding dyad. For this study, home-collected milk samples were requested from the participants under steady-state conditions at the time points 0, 1, 2, 4, 6, 8, 10, 12, and 24 hours postdose. Most of the mothers donated milk samples at the designated time points; however, 2 participants missed 4, 6, 8, 10, 12 hour collections. Mothers were advised to empty both breasts, gently mix the milk, and then aliquot 5 to 10 mL into a provided collection tube. The collected samples were frozen and shipped overnight to our facility, where they are stored at −80°C until further analysis. The HMB was queried for milk donors taking lurasidone, resulting in 9 deidentified volunteers with corresponding milk samples and health questionnaires pertaining to the maternal-infant dyad. Compliance with ethical standards and approval by the relevant institutional review board (IRB # A21-4214) ensure the protection of participant privacy and welfare throughout the HMB. HMB participant deidentification maintains these protections throughout this study.

Lurasidone's clinical activity is primarily driven by the parent compound, with 2 active metabolites (ID-14283 and ID-14326) contributing to its effects to a lesser extent. ID-14283 accounts for approximately 11.4% of total systemic exposure and exhibits receptor binding affinity comparable to that of the parent compound, suggesting a potential contribution to therapeutic effects. ID-14326, present at about 4.1% of exposure, is considered pharmacologically active but likely plays a minimal role due to its low circulating levels. For this study, we focused on the parent compound. The expected milk concentrations of the metabolites would likely be below our detection capacity, as systemic exposures are considerably lower than those of lurasidone itself.

The analysis of lurasidone in human milk was performed using a validated liquid chromatography–mass spectrometry method. Milk samples collected from 9 volunteers were thawed at room temperature. A protein precipitation method was utilized for sample preparation. Briefly, 250 µL of whole milk was combined with 750 µL of acetonitrile containing an internal standard (lurasidone-d8 at 5 ng/mL), and the mixture was vortexed for 5 minutes, followed by centrifugation at 12,000 rpm for 10 minutes at 4°C. The resulting clear supernatant was carefully transferred into liquid chromatography vials for subsequent analysis. Chromatographic separation was achieved on a Phenomenex biphenyl column (4.6 × 100 mm and 2.6 µm particle size) with an isocratic elution method, using 0.1% formic acid in water and 0.1% formic acid in acetonitrile as mobile phases. The mass spectrometry operated in positive electrospray ionization mode, monitoring specific multiple reaction monitoring transitions for lurasidone (m/z 493.3–166.2) and the internal standard (m/z 501.3–166.2). Calibration standards and quality control samples were prepared by spiking blank milk with known concentrations of lurasidone, covering a range of 1.56–200 ng/mL. Validation metrics, including precision, accuracy, linearity, recovery, and sensitivity, were assessed. The limit of detection was 1.56 ng/mL, and limit of quantification was observed as 3.12 ng/mL.

The resulting data provided quantitative concentrations of lurasidone in milk, ensuring reliable and reproducible detection of the compound at low concentrations. Lurasidone exhibits dose-proportional pharmacokinetics within the approved dosing range in healthy adults and clinical populations, ranging from 20 mg to 160 mg daily.[11] To enable a direct comparison of pharmacokinetic parameters and drug exposure estimates between mothers and infants, the maternal lurasidone dose was standardized to 40 mg/day. Accordingly, for mothers originally dosed at 20 mg, 40 mg, 60 mg, or 80 mg/day, the values were multiplied by a factor corresponding to the ratio between 40 mg and the original dose, which also adjusted the standard deviations (SDs) proportionally using the same scaling factor because SD scales linearly. This ensures that variability is accurately represented after dose adjustment. These adjustments were applied before conducting any pharmacokinetic analyses. The pharmacokinetics from the standardized maternal dose of 40 mg/day were further utilized to calculate the RID. The RID was calculated using the equation provided in the FDA's considerations for study design in clinical lactation studies: RID (%) = infant dosage (mg/kg/day)/ maternal dosage (mg/kg/day)* 100.[16] The infant dosage was calculated by assuming an infant intake of 150 mL/kg/day, which simulates a diet of exclusive breast milk, and then multiplied by the average drug concentration determined in milk. A worst-case scenario RID was also calculated using the highest unadjusted individual maximum concentration of drug in milk.

RESULTS

Nine breastfeeding women who were taking lurasidone consented to the HMB between July 2022 and May 2024. Table 1 presents an overview of the demographic characteristics of the women and their infants. The mothers self-administered lurasidone daily, in doses ranging from 20 mg to 80 mg. Lurasidone was quantified in all milk samples provided by the 9 participants, with a mean concentration of 39.5 ng/mL after dose adjustment to 40 mg/day. Understanding the drug concentration-time profile in the milk sample is important for assessing the potential risk of infant exposure and the extent of drug transfer in evaluating the safety of lurasidone use in postpartum lactating

Table 1.
Demographic Characteristics of Participants

Parameter	Mean ± SD (range) (n = 9)
Maternal age, y	33 ± 6.1 (21–42)
Number of pregnancies	5 (1–15)
Maternal weight at time of survey, lb	174 ± 43.4 (115–259)
Gestational age at delivery, wk	39 ± 1.7 (35–41)
Birth weight, g	3,372 ± 397 (2,849–3,997)
	Count (%)
Taking concomitant maternal medications?	
Yes	6 (66.7%)
No	3 (33.3%)
Maternal lurasidone dose	
20 mg	4 (44.5%)
40 mg	1 (11.1%)
60 mg	1 (11.1%)
80 mg	3 (22.2%)
Medical condition(s) for lurasidone use	
Only bipolar disorder	4 (44.5%)
Only depression	1 (11.1%)
Concomitant bipolar disorder and depression	4 (44.5%)
Infant's gender	
Male	3 (33.3%)
Female	6 (66.7%)
Breastfeeding while on lurasidone	9 (100%), all infants were breastfed to some extent
Infant age at time of sampling	
1–3 mo	1 (11.1%)
4–6 mo	4 (44.5%)
7–11 mo	1 (11.1%)
12–23 mo	3 (33.3%)
Infant adverse events suspected via lurasidone exposure?	
Yes	0 (0%)
No	9 (100%)
Infant developmental milestones	
Right on track	6 (66.7%)
Surpassing expectations	3 (33.3%)
Infant health problems	
Poor growth/weight-faltering	1 (11.1%)
Frequent diarrhea	1 (11.1%)
Colic	1 (11.1%)
More than 1 health problem	0 (0%)
NICU admission?	
Yes	2 (22.9%): 1 reason unspecified by mother but could be attributed to pre-term birth at 35 weeks; 1 hypoglycemia
No	7 (77.8%)

Abbreviation: NICU = neonatal intensive care unit.

women. In Figure 1, lurasidone concentrations were adjusted to an intake of 40 mg/day. The concentration peaked at 2 hours but tapered off throughout the dosing interval. To estimate the extent of infant exposure, the RID was calculated by comparing the average milk concentration to the weight-adjusted maternal dose. The RID using mean milk concentrations was 1.16%. Even under the most conservative assumptions, using the highest observed individual concentration of 174 ng/mL, mother taking 80 mg dose, and body weight to be 68 kg, the calculated RID is 3.03%, well below the accepted threshold of 10% for breastfeeding.[17] Table 2 further describes the relevant pharmacokinetic parameters for lurasidone. There were no maternal reports of adverse effects in the exposed infants, all of which were breastfed to some extent.

DISCUSSION

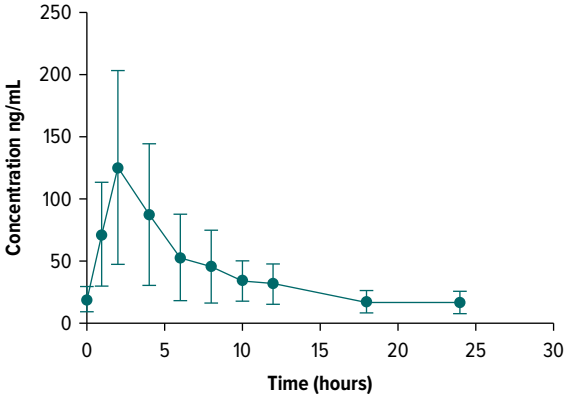
In this study investigating lurasidone concentrations in maternal milk samples, there was low transfer of lurasidone into human milk, even at a dose of 80 mg/day. The RID of lurasidone was 1.16%, which is below the commonly accepted safety threshold of 10% and the stricter threshold of 5% sometimes applied to psychoactive medications.[17] To date, there is only 1 case report available with a lactating mother taking lurasidone 80 mg, which identified a RID of 0.29%.[14]

No adverse events were observed in the breastfed infants in this study. A review of the National Pregnancy Registry for Atypical Antipsychotics compared second-generation antipsychotic use while breastfeeding to a control group of patients with depression and anxiety managed with selective serotonin reuptake inhibitors or selective serotonin norepinephrine reuptake inhibitors and found no adverse effects among exposed infants. It was unclear what percentage of patients were on lurasidone.[7] The reproductive safety of lurasidone was evaluated in another trial, and it was found that the absolute risk of major malformations was comparable between lurasidone (2.19%), quetiapine (1.85%), and the control group (1.77%).[18]

Antipsychotics carry potential risks of gestational diabetes, weight gain, metabolic syndrome, and insulin resistance. The ACOG guidelines strongly recommend, based on moderate-quality evidence, to screen pregnant individuals on antipsychotics for gestational diabetes mellitus due to the potential risks.[10] While there are concerns about several atypical antipsychotics, the ACOG guidelines comment that lurasidone may confer certain advantages regarding minimization of metabolic complications.[10] Breastfeeding can also minimize and reduce metabolic complications. Breastfeeding for at least 6 months decreases the maternal risk of hypertension, diabetes, hyperlipidemia, and elevated body mass index, which are factors of metabolic syndrome.[19] There is evidence from a systematic review and meta-analysis in nonpregnant patients with schizophrenia, not bipolar disorder, that indicates lurasidone usage did not significantly impact the weight, body mass index, total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, or triglycerides. Interestingly, glucose concentrations were reduced with lurasidone compared to placebo in this analysis.[20] The antipsychotics that have demonstrated the highest risk of

Figure 1.

Average Concentration of Lurasidone in Milk (n = 9), Adjusted to an Intake of 40 mg/day[a]



[a]Bars represent standard deviation.

Table 2.

Calculated Pharmacokinetic Parameters of Lurasidone (n = 9); Concentrations Adjusted to an Intake of 40 mg/day

Parameter	Mean ± SD (n = 9)
AUC, ng × h/mL	948 ± 333
C_{avg}, ng/mL	40 ± 13.8
C_{max}, ng/mL	121 ± 44
T_{max}, h	2
Infant dose, mg/kg/d	0.006 ± 0.002
Maternal dose, mg/kg/d	0.5 ± 0.1

Abbreviation: AUC = area under the curve.

metabolic syndrome among all second-generation antipsychotics are clozapine and olanzapine.

Coincidentally, a study of breastfeeding mothers in the puerperium period evaluated infant safety with antipsychotic exposure. The majority of the antipsychotic case reports did not have significant infant adverse events reported. Clozapine had rare case reports of agranulocytosis (N = 1), lethargy (N = 1), and delayed speech acquisition (N = 1). Olanzapine had case reports of jaundice and sedation (N = 1); shaking, poor sucking, and lethargy (N = 1); protruding tongue (N = 1); diaper rash, diarrhea, and sleep disorder (N = 1); and temporary motor development delay (N = 1).[21] Despite these concerns, olanzapine is a first-line agent during breastfeeding, but may require increased infant monitoring for drowsiness, irritability, poor feeding, and extrapyramidal symptoms. With clozapine, other agents may be preferred; however, if used, it is prudent to monitor for sedation and white blood cell counts.

Lurasidone is an attractive option for breastfeeding women based on its safety and metabolic profiles. There are no strong reports or indicators of infant harm noted. It also does not appear to impact milk production. Lurasidone does have significant drug-drug interactions involving CYP3A4 inhibitors (eg, grapefruit juice, ritonavir, itraconazole, erythromycin, diltiazem) and CYP3A4 inducers (eg, carbamazepine, phenytoin, rifampin). Using lurasidone concomitantly with a CYP3A4 inhibitor can significantly increase the serum concentration of lurasidone. Therefore, it is recommended to reduce the lurasidone dose when used in combination with medications that inhibit CYP3A4. Lurasidone usage with CYP3A4 inducers is contraindicated and warrants alternative therapy selection due to decreased lurasidone concentrations. Lurasidone has unique administration recommendations to be taken consistently at the same time each day, preferably with food (≥350 calories). Administering lurasidone at night may help mitigate some adverse effects.

Concerning other options for managing bipolar depression, there is no information regarding the transfer or cariprazine into human milk, but the half-life of the didesmethyl cariprazine metabolite can be up to 3 weeks in adults, and there is a case of tardive dyskinesia in an infant with in utero and milk exposures to cariprazine.[22] An analysis of lumateperone, including 17 women, identified a RID of 0.06% but did not evaluate effects on the breastfed infant or how lumateperone impacts milk production.[23] An analysis of quetiapine from case reports, including 8 women, identified a RID of 0.09% to 0.43%.[24] The maternal weight-adjusted dosage of olanzapine ranges from 0.22% to 1.6%.[25–29] The maternal weight-adjusted dosage of fluoxetine and its metabolite ranges from 2.4 to 12%.[30,31] The package insert for the combination of olanzapine and fluoxetine does not report any maternal weight-adjusted dosages or RIDs.[32]

Lurasidone may be used in combination with lithium therapy, but this study did not have any women on concomitant therapy. Lithium may be preferable in the peripartum period over valproate due to the risk of recurrence or exacerbation of mood symptoms with valproate and risk for congenital malformations, but lithium is not without its risks. ACOG recommends that pregnant patients taking lithium in the first trimester receive a detailed ultrasound examination in the second trimester, which is a strong recommendation with moderate quality evidence. Lithium enters breastmilk and has an average RID of 12.2%, ranging from 0% to 30%.[33] During pregnancy and postpartum, maternal lithium levels should be checked as well as infant lithium levels due to infant kidney function changes or dehydration. Lithium can also impact maternal and infant thyroid levels, so it is prudent to monitor thyroid function routinely.[22]

This study has several limitations. The observational design rooted in maternally reported questionnaire data leaves gaps in maternal and infant histories. Significantly, the extent of drug exposure to the infant

via milk is poorly understood. The sample size is small, and the analysis is limited to milk only. Although not required for lactation trials, complementary maternal and infant blood analysis would have made the analysis more robust, as would including analysis of the two active metabolites that account for ~15% of lurasidone's clinical activity. While this study included maternal weight changes, there was limited information on other metabolic syndrome factors, which are also essential monitoring parameters for second-generation antipsychotics. Confounding exposures during pregnancy make it difficult to draw conclusions about infant outcomes.

CONCLUSION

In this analysis of 9 lactating mothers taking lurasidone up to 80 mg, the RID of 1.16% was well below the 5% to 10% safety threshold for breastfeeding infants. This study adds to the knowledge that lurasidone has a low RID and is unlikely to cause infant harm for breastfeeding mothers requiring antipsychotic treatment. There is an important risk/benefit profile between maternal antipsychotic use and breast-fed infant exposure to the medications.[21] Based on the available evidence, there is a notable risk of harm to the maternal-infant dyad in an untreated mother who chooses to forgo antipsychotic treatment in favor of breastfeeding (eg, mood relapse in the mother, with suicide and infanticide as very real risks). Simultaneously, breastfeeding provides immunological and developmental benefits to the breastfed infant along with dose-intense risk reductions in cancers and cardiovascular disease for the lactating mother.[34] Consequently, it is advisable to follow the ACOG guideline recommendations to not discontinue mood stabilizers except for valproate during peripartum. Findings from our research demonstrate minimal transfer of lurasidone into breast milk, supporting the safety of breastfeeding for women requiring this medication. This evidence allows mother-infant pairs to benefit from the numerous health advantages of breastfeeding while maintaining effective maternal psychiatric treatment without fear of harming their infant.

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