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Obstetric Outcomes With Second-Generation Long-Acting Injectable Versus Oral Antipsychotics

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Abstract

Objective: The purpose of this study is to evaluate obstetric outcomes in pregnant women who received second-generation long-acting injectable antipsychotics (LAIAs) compared to a control group who received second-generation oral antipsychotics.

Methods: This was a retrospective study utilizing a global cohort of 148 health care organizations grouped into a network within the TriNetX database. Pregnant patients of any trimester were grouped into 2 cohorts: (1) exposure to long-acting aripiprazole, risperidone, paliperidone, or olanzapine (n = 2,082) and (2) exposure to the corresponding oral formulations (n = 31,376) and propensity matched. The primary outcome was the occurrence of one of the following obstetric complications: gestational diabetes, preeclampsia, eclampsia, or a newly diagnosed hypertensive disorder. Cesarean section rates were also assessed.

Results: After propensity matching, each cohort yielded 2,025 patients. No intergroup differences were observed in the composite primary end point, performed postmatching (odds ratio 0.95; 95% CI, 0.76–1.18; *P* = .61). No difference in rates of cesarean section was observed.

Conclusion: Similar rates of gestational diabetes, eclampsia, preeclampsia, and maternal hypertensive disorders were observed in women receiving long-acting injectable and oral second-generation antipsychotics.

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Antipsychotics are increasingly being prescribed to manage psychiatric illnesses such as schizophrenia and bipolar disorder during pregnancy. For those with severe illness, the risk of peripartum relapse may outweigh the risk of in utero antipsychotic exposure. Untreated or inadequately treated maternal psychiatric illness is associated with poor adherence to treatment, reduced prenatal care, increased use of alcohol or tobacco, and disruptions to family dynamics.[1–3]

Retrospective and prospective data suggest that fetal exposure to oral antipsychotics is generally associated with a low risk of major teratogenicity and adverse neurodevelopmental outcomes, with the exception of risperidone and paliperidone that may pose a marginally higher risk of major teratogenic effects.[4,5] Concerns about the use of antipsychotics during pregnancy are not limited to neonatal complications; obstetric complications are also important considerations. Second-generation antipsychotic (SGA) use during pregnancy has been associated with an increased risk of developing gestational diabetes, maternal hypertensive disorders, or other adverse obstetric outcomes.[6–8] In line with these concerns, the American College of Obstetricians and Gynecologists recommends monitoring for gestational diabetes in pregnant patients who require antipsychotic treatment.[9]

While much of the existing research focuses on oral antipsychotic use during pregnancy, there is growing interest in understanding outcomes related to long-acting injectable antipsychotics (LAIAs). LAIAs provide several benefits for individuals with serious mental illness and are recommended for patients who have demonstrated both response and tolerability to the corresponding oral formulation, especially in cases where patients prefer this modality or have a history of poor adherence to antipsychotic treatment.[1] LAIAs are often underutilized despite literature supporting their benefit in reducing psychiatric relapse hospitalization rates compared to oral antipsychotics.[10–12] Further, in patients with severe illness or documented nonadherence, LAIAs have improved treatment retention and prolonged the time to medication discontinuation.[11,13] By offering consistent medication exposure and reducing nonadherence, a driver for illness relapse, LAIAs

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Clinical Points

- Evidence on obstetric outcomes following maternal exposure to long-acting injectable antipsychotics is limited.
- When comparing obstetric outcomes in second-generation long-acting injectable versus oral antipsychotics, no differences in gestational diabetes or maternal hypertensive disorders were observed.
- Long-acting injectable antipsychotics may be safe to continue or initiate when considering obstetric complications, particularly in pregnant women where the risk of untreated illness outweighs medication-related adverse effects.

may play a crucial role in managing psychiatric illness during pregnancy.

Despite these potential benefits, there is a paucity of literature regarding the safety of LAIAs in pregnancy. It remains unclear whether study findings from oral antipsychotics can be extrapolated to LAIAs, as most available data for LAIAs are limited to case reports, case series, and small retrospective reviews.[14,15]

The purpose of this study is to evaluate obstetric outcomes in pregnant women who received second-generation LAIAs compared to a control group who received second-generation oral antipsychotics. The authors hypothesize that there is no difference in obstetric outcomes between oral and LAIA exposure in pregnant women.

METHODS

Study Design and Data Source

This was a retrospective study utilizing a global cohort of 148 health care organizations grouped into a network within the TriNetX database called the Global Collaborative Network. TriNetX is a global federated health research network providing deidentified access to retrospective electronic medical records across academic and nonacademic health care organizations. Diagnosis, laboratory measures, medications, and hospitalization data are available for 73 million patients in the US and 88 million patients globally through this platform. Because only deidentified data were used, this study was exempt from institutional review board review in accordance with institutional policy. This study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines for reporting clinical research.[16]

Cohort Selection

Pregnant patients greater than age 18 years were grouped into 2 cohorts: (1) exposure to an LAIA (aripiprazole, risperidone, paliperidone, or olanzapine) 7 days before or 280 days after a coded pregnancy event and (2) exposure to oral aripiprazole, risperidone, paliperidone, or olanzapine within 14 days before or 280 days after a coded pregnant event. While those exposed to LAIAs were excluded from the oral SGA cohort, oral antipsychotic exposure was permitted for the LAIA cohort, given that several LAIAs require oral antipsychotic overlap for a period of time.

Index Event and Time Window Definition

The index event, marking the start of the observation period, was defined separately for each cohort to account for pharmacokinetic differences between oral and LAIAs. The index event for the oral antipsychotic cohort was defined as oral antipsychotic administration in the 7 days before or within 280 days after a pregnancy event was coded (n = 33,458). In the LAIA cohort, to account for the prolonged duration of action, the index event was set as an LAIA administered 14 days before or within 280 days of a pregnancy event being coded (n = 2,082). Obstetric outcomes from antipsychotic exposure during all trimesters were evaluated. The time window for outcomes assessed included events started 1 day after the first occurrence of the index event and ended 280 days after the first occurrence of the index event.

International Statistical Classification of Diseases, Tenth Revision (*ICD-10*), Current Procedural Terminology (CPT), Systematized Nomenclature Of Medicine Clinical Terms (SNOMED CT), normalized drug names (RxNorm), and Healthcare Common Procedure Coding System (HCPCS) codes were utilized to identify obstetric outcomes and medications. Other obstetric outcomes that are more likely to occur in the first trimester, including spontaneous abortion, were not included.[17] Congenital malformations were also not assessed due to limitations within the platform in maternal-neonatal chart linkage. In this dataset, only select neonatal outcomes documented after birth are recorded in the mother's chart, limiting the ability to fully evaluate neonatal outcomes. Because 80% of spontaneous abortions occur within the first 12 weeks of gestation, this outcome was not assessed.

The primary outcome was the occurrence of one of the following obstetric complications: gestational diabetes, preeclampsia, eclampsia, or a newly diagnosed hypertensive disorder. Secondarily, individual outcomes were assessed along with the odds of cesarean section.

Statistical Analysis

To create balanced comparison populations, propensity score matching (PSM) was performed in a 1:1 ratio. Matching criteria included 26 different features. These criteria included relevant demographic information such as age and race, social determinants of health, medical and psychiatric

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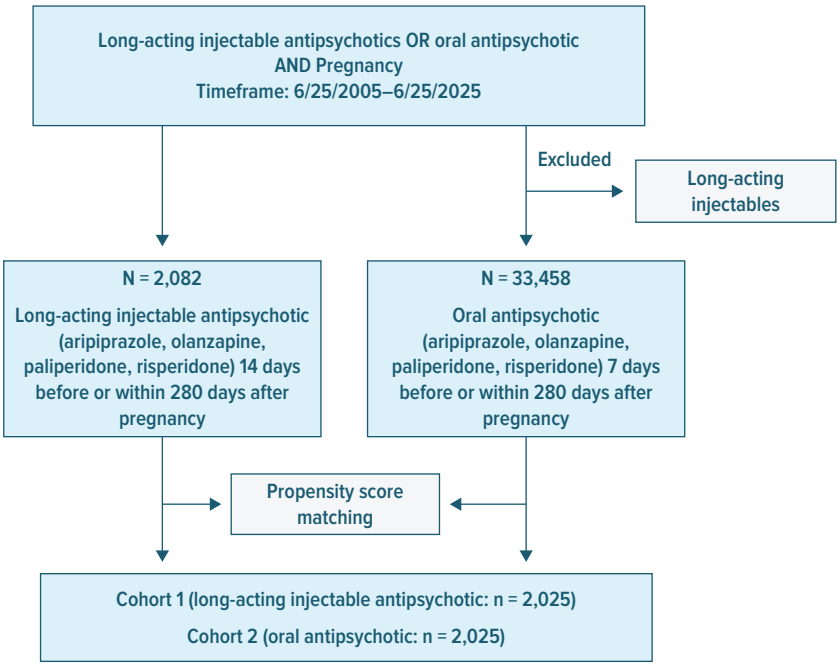
Figure 1.
Cohort Formation



conditions, and concomitant psychotropic use. Psychiatric conditions such as schizophrenia, bipolar disorder, major depressive disorder, and anxiety disorders were included in the PSM along with comorbid medical conditions such as diabetes mellitus and circulatory disorders. Use of lithium, valproic acid derivatives, antidepressants, and sedatives/hypnotics were also included. Information collected within the platform for cohort creation and matching was queried with relevant *ICD-10* diagnostic codes and RxNorm medication codes.

To ensure the matched patient cohorts were balanced, a standardized mean difference (SMD) of less than 0.1 was considered adequately matched for each matching feature utilized.[18] Statistical analysis using a measure of association was performed within the TriNetX platform to calculate and compare the odds of experiencing the primary outcome or any of the individual obstetric outcomes. The measure of association included calculation of unadjusted odds ratios (ORs) derived from 2×2 contingency tables. ORs were calculated comparing the frequency of the use of each medication between the two cohorts. Reported *P* values less than .05 were considered statistically significant for each comparison.

RESULTS

With the initial TriNetX search, 31,376 patients met criteria for inclusion in the oral cohort, and 2,082 patients met criteria for inclusion in the LAIA cohort (Figure 1). After PSM, 2 cohorts of 2,025 patients were created for subsequent analyses. All matching covariates achieved adequate balance, with SMDs below 0.1. The mean age was 30 years, and White (47%) and Black (40%) patients were the most commonly represented races. Bipolar disorder (47%) and schizophrenia (30%) were the most common antipsychotic indications reported. Anxiety disorders, major depressive disorder, and nicotine use disorder were also diagnosed in 44%, 39%, and 42% of patients, respectively. Antidepressant (61%) and sedative/hypnotic (66%) prescriptions were common. Thirty-four percent of patients were diagnosed with underlying circulatory disorders, and 11% had preexisting diabetes mellitus. The maximum standardized difference of matched cohorts was 0.095, suggesting a good balance of measured characteristics. Table 1 includes a detailed description of cohort demographics at baseline and after matching.

The primary outcome was observed in 8.7% of patients on oral SGAs and 8.3% of patients on corresponding LAIAs. When comparing cohorts, the composite primary end point, performed postmatching, showed no statistical or clinical difference in any obstetric complication between long-acting and oral SGAs (OR 0.95; 95% CI, 0.76–1.18; $P = .612$).

Assessing individual components of the composite end point, no statistically or clinically significant differences were observed when comparing rates of a new diagnosis of gestational diabetes, preeclampsia,

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Table 1.

Baseline Characteristics of Both Cohorts Before and After Propensity Score Matching

	Initial populations					Propensity score matched populations				
	Cohort 1: LAIAs (n = 2,082)		Cohort 2: Oral SGAs (n = 31,376)			Cohort 1: LAIAs (n = 2,025)		Cohort 2: Oral SGAs (n = 2,025)		
	n	%	n	%	*P* value	n	%	n	%	*P* value
Age, mean (SD), y	30.4 (8.5)		33.8 (14.5)		<.001	30.5 (8.6)		29.9 (9.0)		.056
White	959	46.1	18,897	60.7	<.001	947	46.8	920	45.5	
Hispanic or Latino	160	7.70	3,314	10.6	<.001	158	7.80	110	5.40	.002
Black or African American	834	40.1	6,405	20.6	<.001	793	39.2	823	40.6	.336
Asian	23	1.10	765	2.50	<.001	22	1.10	17	0.80	.421
Diagnosis (ICD code, if applicable)										
Overweight, obesity and other hyperalimentation (E65–E68)	634	30.5	7,299	23.4	<.001	607	30	571	28.2	.213
Diabetes mellitus (E08–E13)	238	11.4	3,093	9.90	.027	229	11.3	231	11.4	.921
Diseases of the circulatory system (I00–I99)	745	35.8	10,941	35.1	.047	720	35.6	656	32.4	.034
Nicotine dependence (F17)	909	43.7	8,122	26.1	<.001	862	42.6	817	40.3	.151
Alcohol-related disorders (F10)	278	13.4	2,833	9.10	<.001	265	13.1	218	10.8	.186
Multiple gestation (O30)	51	2.50	675	2.20	.39	48	2.40	36	1.80	.186
Unspecified maternal hypertension (O16)	194	9.30	1,925	6.20	<.001	187	9.20	204	10.1	.366
Opioid-related disorders (F11)	217	10.4	2,748	8.80	.013	211	10.4	171	8.40	.032
Schizophrenia (F20)	665	32.0	1,863	6.00	<.001	614	30.3	606	29.9	.784
Schizoaffective disorders (F25)	548	26.3	1,290	4.10	<.001	494	24.4	499	24.6	.855
Cannabis-related disorders (F12)	614	29.5	3,982	12.8	<.001	574	28.3	511	25.2	.025
Other stimulant-related disorders (F15)	289	13.9	1,680	5.40	<.001	267	13.2	252	12.4	.481
Bipolar disorder (F31)	1,011	48.6	8,724	28.0	<.001	960	47.4	934	46.1	.413
Persons with potential health hazards related to socioeconomic and psychosocial circumstances (Z55–Z65)	638	30.7	4,128	13.3	<.001	594	29.3	546	27.0	.094
Major depressive disorder, single episode, unspecified (F32.9)	830	39.9	10,794	34.7	.005	799	39.5	780	38.5	.540
Anxiety disorder, unspecified (F41.9)	944	45.4	12,451	40.0	<.001	910	44.9	853	42.1	.071
Disorders of thyroid gland (E00–E07)	237	11.4	3,886	12.5	.146	227	11.2	229	11.3	.921
Medications										
Lithium (CN750)	303	14.6	1,411	4.50	<.001	274	13.5	285	14.1	.616
Valproate (40,254)	349	16.8	1,745	5.60	<.001	308	15.2	284	14.0	.286
Antidepressants (CN600)	1,313	63.1	17,617	56.6	<.001	1,266	62.5	1,208	59.7	.062
Sedatives/hypnotics (CN300)	1,442	69.3	17,578	56.4	<.001	1,388	68.5	1,277	63.1	.001

Abbreviations: LAIA = long-acting injectable antipsychotic, SGA = second-generation antipsychotic, SD = standard deviation, y = years.

eclampsia, or gestational hypertension. Secondarily, comparisons of cesarean sections between groups were not significant (OR 1.09; 95% CI, 0.83–1.43; *P* = .537; Table 2).

DISCUSSION

In this large, retrospective matched cohort analysis using real-world data from TriNetX, there was no statistically or clinically significant difference observed in obstetric outcomes among patients receiving second-generation LAIAs vs oral. After robust propensity score matching, no differences in the composite of gestational diabetes, preeclampsia, eclampsia, or gestational hypertension or cesarean deliveries were observed. These findings suggest that LAIAs may result in similar obstetric outcomes as oral SGAs and may be considered safe options for pregnant women with serious mental illness. Notably, providing safety data on LAIAs relative to oral antipsychotics expands available treatment options, allowing clinicians to better support medication adherence and reduce maternal relapse. Additionally, expanding use may confer benefits beyond pregnancy by reducing the risk of postpartum psychosis and mood episodes, as seen with oral antipsychotics in the peripartum period.[19]

Literature on outcomes associated with LAIA exposure in pregnancy is scant and descriptive in nature, with most limited to case reports and series or retrospective analysis with small sample sizes and no comparator group. The National Pregnancy Registry for Atypical Antipsychotics is currently enrolling patients prospectively on LAIAs; however, limited data are available on LAIA use in pregnancy to date. Further, studies of antipsychotic exposure during pregnancy have mostly focused on congenital malformations rather than the obstetric outcomes evaluated in this study.[4,20–24] Gestational diabetes has been the focus of most studies evaluating obstetric outcomes with antipsychotic

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Table 2.
Odds of Obstetric Complications

	Cohort 1: LAIAs		Cohort 2: Oral SGAs			
	n	%	n	%	Odds ratio (95% CI)	*P* value
Any obstetric outcome	168	8.3	177	8.7	0.95 (0.76–1.18)	.612
Secondary end points						
Gestational diabetes	48	2.4	53	2.6	0.9 (0.61–1.34)	.614
Preeclampsia, eclampsia, or maternal hypertension	136	6.7	148	7.3	0.91 (0.72–1.16)	.46
Cesarean section	117	5.8	108	5.3	1.09 (0.83–1.43)	.537

Abbreviations: LAIA = long-acting injectable antipsychotic, SGA = second-generation antipsychotic.

exposure. In one systematic review, antipsychotic drug exposure was associated with 2.6% to 22% prevalence rates of gestational diabetes compared to 0.95% to 10.7% prevalence rate in women who were not exposed to antipsychotics.[25] The lack of significant association with gestational diabetes in the current study is in contrast to a previous study of Medicaid enrollees who received at least 2 or more prescriptions of antipsychotics during the first half of the pregnancy.[7] The adjusted relative risks for gestational diabetes were increased for olanzapine (1.61; 95% CI, 1.13–2.29) and quetiapine (1.28; 95% CI, 1.10–1.62). In one Finnish study, the use of any antipsychotic was associated with higher risk of gestational diabetes mellitus (adjusted odds ratio [aOR] 1.64; 95% CI, 1.19–2.27) and increased postpartum bleeding in vaginal delivery (aOR 1.50; 95% CI, 1.09–2.07).[26] The lack of similar findings in this study could be attributed to differences in populations studied and the respective risks of gestational diabetes (11% had preexisting diabetes mellitus in this study).

Similar to our findings, a small prospective case series of 15 patients with psychosis from Italy on either paliperidone or aripiprazole LAI showed that LAI exposure in pregnancy was not associated with an increased risk of gestational diabetes or obstetrical complications.[27]

One retrospective review of 12 case reports for 13 pregnancies documented birth and neonatal outcomes in patients who received several different LAIAs (mostly risperidone and paliperidone).[28] Three of 11 delivery methods reported were via cesarean section, a rate similar to the general population. No reports of gestational diabetes and no commentary on the association of preeclampsia or other maternal hypertensive disorders were reported. Two instances of maternal hypertension were reported but attributed to cigarette smoking. Cigarette smoking status was not available for the current study and could be a factor in gestational hypertension.

Outcomes related to LAIA administration were reported in 38 pregnancies over an 18-year period in a tertiary maternity hospital in Australia.[15] SGAs were prescribed in 14 of the 38 pregnancies, with aripiprazole comprising more than half of the LAIAs prescribed. Fifty percent of these patients (n = 7) also received oral antipsychotic supplementation in addition to the LAIA. In contrast to the current study, preeclampsia and pregnancy-induced hypertension were noted in 8% of patients, compared to the 2% reported in state population data of women not receiving LAIAs. The majority of patients did not receive screening for gestational diabetes, though gestational diabetes was noted in 50% of patients screened (n = 7). Emergency cesarean section was reported in 29% of LAIA pregnancies compared to 17% in the state population; however, this difference was not statistically significant. Although the study provides valuable insight into obstetric outcomes among women receiving LAIAs, the comparator group consisted of women not exposed to antipsychotics. This limits the direct comparability of its findings to the outcomes observed in our analysis.

LAIAs differ pharmacokinetically from oral antipsychotics by having prolonged elimination half-lives and fewer peak-to-trough fluctuations. The prolonged elimination half-life is often viewed favorably as it supports adherence, reduces maternal relapse risk, and may mitigate peak-related adverse effects.[11–13,29,30] However, theoretically, higher sustained trough concentrations with LAIAs could increase fetal drug exposure. It is important to note that this remains speculative and has not demonstrated validity in clinical studies.

Like all retrospective database studies, our analysis has limitations including potential incomplete or variable coding or reporting practices. Further, not all maternal and neonatal outcomes or relevant confounders, including severity of maternal psychiatric illness, were consistently available in TriNetX or could be restricted to the pregnancy timeframe for inclusion. We were not able to individually characterize patients or quantify the duration or extent of individual antipsychotic exposure. We also did not evaluate individual antipsychotics and their risks for obstetric outcomes since the focus of the study was to compare the differences in oral versus long-acting injectable antipsychotics.

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CONCLUSION

Similar obstetric outcomes were observed in pregnant women receiving long-acting injectable and oral second-generation antipsychotics. No difference in rates of gestational diabetes, eclampsia, preeclampsia, or maternal hypertensive disorders was observed. LAIAs may be safe to continue or initiate when considering obstetric complications, particularly in pregnant women where the risk of untreated illness outweighs medication-related adverse effects. However, additional research is needed to better understand neonatal safety following in utero exposure to LAIAs.

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