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Continuation versus Discontinuation of Statins during Pregnancy: A Comparative Analysis of Maternal and Neonatal Risks

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Abstract

This study aimed to evaluate the effect of continuing or discontinuing statin therapy during pregnancy on maternal lipid profile, maternal complications, and neonatal outcomes in women who took statins before pregnancy. A retrospective cohort study included 180 women who took statins before pregnancy and delivered at perinatal centers in Vladikavkaz between 2021 and 2025. Participants were divided into two groups: those who continued statins during pregnancy (n=94) and those who discontinued therapy upon pregnancy recognition (n=86). Demographic data, lipid profiles at four time points, maternal outcomes (preeclampsia, gestational diabetes, preterm birth, cesarean section, postpartum hemorrhage), and neonatal outcomes (Apgar score, birth weight, low birth weight, congenital anomalies, NICU admission) were assessed. In the discontinuation group, LDL cholesterol increased from 2.5 mmol/L before pregnancy to 4.3 mmol/L in the third trimester. In the continuation group, LDL levels remained stable (2.4–2.7 mmol/L). The decision to continue therapy was made by 52.2% of women and was independently associated with familial hypercholesterolemia and a history of cardiovascular events. Maternal complications did not differ between groups. Statin continuation was associated with lower neonatal birth weight (3180 g vs. 3350 g, p=0.031) and a trend toward higher low birth weight (9.6% vs. 3.5%, p=0.096). Congenital anomalies were comparable between groups (1.1% vs. 1.2%). Discontinuing statins during pregnancy leads to a marked increase in LDL cholesterol but is not associated with increased maternal complications.

Keywords: Statins, Pregnancy, Lipid profile, LDL cholesterol, Familial hypercholesterolemia, Congenital anomalies

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Introduction

Cardiovascular diseases remain the leading cause of death among women worldwide, and dyslipidemia plays a key role in their development. Over recent decades, the prevalence of dyslipidemia has reached epidemic proportions. According to a systematic review and meta-analysis, the global prevalence of hypercholesterolemia among adults is approximately 24%, while elevated low-density lipoprotein cholesterol (LDL-C) is detected in nearly 19% of adults (Ballena-Caicedo *et al*., 2025). Significant regional differences exist, with the highest rates of low high-density lipoprotein cholesterol (HDL-C) and mixed dyslipidemia observed in the Middle East and Latin America. A concerning trend is the progressive increase in hypertriglyceridemia and low HDL-C, indicating an epidemiological transition in lipid disorders (Ballena-Caicedo *et al*., 2025). This problem is particularly important among women of reproductive age, as dyslipidemia not only increases the risk of cardiovascular events in the mother but may also adversely affect pregnancy outcomes and offspring health (Noubiap *et al*., 2022; Svendsen *et al*., 2025).

Statins, inhibitors of HMG-CoA reductase, are the cornerstone of pharmacotherapy for dyslipidemia and the mainstay of primary and secondary cardiovascular prevention. In women of reproductive age, statins are prescribed for several life-saving indications. Familial hypercholesterolemia (FH), an autosomal dominant genetic disorder characterized by extremely elevated LDL-C from birth, occurs with a frequency of approximately 1 in 250 individuals in the general population and, left untreated, leads to atherosclerosis and cardiovascular events at a young age (Abifadel & Boileau, 2023; Mulder *et al*., 2025). Beyond FH, indications for statin therapy in young women include a history of acute coronary syndrome, ischemic stroke, myocardial revascularization, as well as type 2 diabetes mellitus with target organ damage and metabolic syndrome (Visseren *et al*., 2022).

Furthermore, substantial gender differences exist in statin prescribing: women are less likely than men to achieve LDL-C targets, more often experience delays in treatment initiation, and have higher rates of therapy discontinuation, due to both biological factors and systemic issues in healthcare delivery (Graham & Raal, 2021; Colvin *et al*., 2021; Almotawah *et al*., 2023; Ansari *et al*., 2023; Stoev *et al*., 2023; Li *et al*., 2024; Samaranayake *et al*., 2024; Son & Lee, 2024; Prada *et al*., 2024; Rodriguez *et al*., 2025).

Until recently, statins were absolutely contraindicated during pregnancy and were classified as category X by the US Food and Drug Administration (FDA). This classification was based on animal studies demonstrating teratogenic effects at doses many times higher than therapeutic human doses (Edison & Muenke, 2004; Bittencourt, 2022). However, observational studies in humans over the past two decades have not confirmed a significant increase in the risk of congenital anomalies with first-trimester statin exposure (Karadas *et al*., 2022; Khalili *et al*., 2025; Christensen *et al*., 2026). A key event was the FDA's July 2021 decision to remove the category X label from all statins. In its official statement, the FDA noted that "the benefits of statins may include prevention of serious or potentially fatal events in a small group of patients at very high risk" and that "contraindication of these drugs for all pregnant women is not appropriate." At the same time, the FDA emphasized that for most patients, statins should be discontinued upon pregnancy recognition, although individualized decisions to continue therapy may be made in cases of extremely high cardiovascular risk (Bittencourt, 2022).

The evolving understanding of statin use in pregnancy has led to a new clinical paradigm based on individualized risk-benefit assessment. The European Society of Cardiology, in its guidelines, allows continuation of statin therapy during pregnancy in patients with documented coronary atherosclerosis (Pham *et al*., 2022). Particular attention is paid to drug selection: hydrophilic statins, especially pravastatin, are preferred during pregnancy because they are substrates of P-glycoprotein, an efflux pump that limits placental transfer. Experimental studies show that pravastatin concentrations in fetal tissues are only about 30% of maternal levels (Bittencourt, 2022). Lipophilic statins (atorvastatin, simvastatin) readily cross the placenta and are potentially less safe for the fetus; therefore, switching from a lipophilic to a hydrophilic statin is recommended when continuation of therapy is necessary (Bittencourt, 2022; Ghelfi *et al*., 2025; Lins Serafim *et al*., 2025).

Despite changes in the regulatory framework, clinical guidelines remain fragmentary, and the management of pregnancy in women taking statins is characterized by considerable variability (Mohammadi *et al*., 2024; Nugraha *et al*., 2024; Suyunbaevna *et al*., 2024). Key unresolved issues include assessment of cardiovascular risk when statins are discontinued during pregnancy, lipid profile dynamics across trimesters, fetal safety of continued therapy, and long-term outcomes of children exposed to statins in utero (Bittencourt, 2022; Gera *et al*., 2025). Large nationwide cohort studies from South Korea and Norway have demonstrated that statin discontinuation during pregnancy is not associated with an increased risk of cardiovascular events in the mother, even in very high-risk subgroups (patients with FH or documented atherosclerotic cardiovascular disease) (Cho *et al*., 2026). Moreover, statin discontinuation was associated with more favorable fetal outcomes, including lower risks of stillbirth and low birth weight (Cho *et al*., 2026). The Norwegian nationwide study found no statistically significant association between first-trimester statin use and the risk of congenital anomalies, and an updated meta-analysis similarly confirmed no increased risk of major malformations (Chang *et al*., 2021; Kay *et al*., 2025).

A recent Japanese nationwide consultation-based cohort study (n = 968) similarly found no significant increase in congenital anomalies following first-trimester statin exposure (1.6% vs. 1.6%). However, higher risks of preterm birth and low birth weight were observed in weighted analyses (Fujioka *et al*., 2026). A 2025 systematic review and meta-analysis of 11 studies (10,482 women) reported a pooled relative risk for preeclampsia of 0.78 (95% CI: 0.33–1.83, p = 0.57), indicating no statistically significant association, though high heterogeneity (I^2 = 94%) and potential benefits of early initiation were noted (Costantine *et al*., 2021; Rao *et al*., 2022). Recent clinical reviews have reinforced that pravastatin is considered safer than other statins for use during pregnancy, with no reports of abnormal pregnancy outcomes (Akbar *et al*., 2024; Lins Serafim *et al*., 2025).

At the same time, several questions remain open. Some studies suggest that statin use during pregnancy may be associated with an increased risk of preterm birth and low birth weight, warranting further investigation (Chang *et al*., 2021; Kay *et al*., 2025). Moreover, data on long-term outcomes of children exposed to statins in utero, including neurocognitive development and metabolic profiles, are largely absent (Kay *et al*., 2025). Particular concern centers on the effects of statins on fetal cholesterol synthesis, as cholesterol is critically important for myelination of the nervous system, synaptogenesis, and steroid hormone synthesis (Svendsen *et al*., 2025).

In the Russian Federation, studies analyzing clinical practice regarding pregnancy management in women taking statins are virtually nonexistent (Mulu *et al*., 2023; Najjar, 2023). It is unknown what the actual frequency of statin prescribing is among Russian women of reproductive age, which factors influence the decision to continue or discontinue therapy upon pregnancy recognition, what the dynamics of lipid profile are across trimesters in women with discontinued versus continued statin therapy, and which maternal and neonatal outcomes are associated with each approach in real-world clinical practice.

The aim of this study was to evaluate the effect of continuing versus discontinuing statin therapy during pregnancy on maternal lipid profile dynamics, maternal complication rates, and neonatal outcomes in women who took statins before pregnancy, based on data from perinatal centers in Vladikavkaz for the period 2021–2025.

Materials and Methods

A retrospective cohort study was conducted, approved by the local ethics committee of North Ossetian State Medical Academy (Vladikavkaz, Republic of North Ossetia-Alania, Russia). Due to the retrospective nature and use of anonymized data, informed consent was not required. The study was performed at perinatal

centers in Vladikavkaz, including data from pregnant women followed and delivered at these centers between January 1, 2021, and December 31, 2025.

Inclusion criteria were statin use for at least three months before pregnancy, singleton pregnancy, gestational age at delivery between 37 and 42 weeks, complete lipid profile data in at least two time points (before pregnancy and in one trimester), and availability of maternal and neonatal outcome data. Exclusion criteria were multiple pregnancy, preterm birth (<37 weeks), severe extragenital pathology (decompensated heart defects, end-stage renal disease, oncological diseases), and absence of data on statin use during pregnancy or lipid profile at the analyzed time points (Babaei *et al*., 2024; Karthikeyan *et al*., 2024; Kovalchuk *et al*., 2024).

All included women were divided into two groups based on whether they continued statin therapy after pregnancy recognition. The causal relationships between baseline factors, the decision to continue or discontinue statins, lipid profile dynamics, and maternal-neonatal outcomes are illustrated in **Figure 1**. The main group (Group 1) consisted of 94 women who continued statins during pregnancy at any dose and for any duration. The comparison group (Group 2) consisted of 86 women who took statins before pregnancy but discontinued them upon pregnancy recognition in the first trimester and did not take any statins throughout pregnancy. The total sample size was 180 patients.

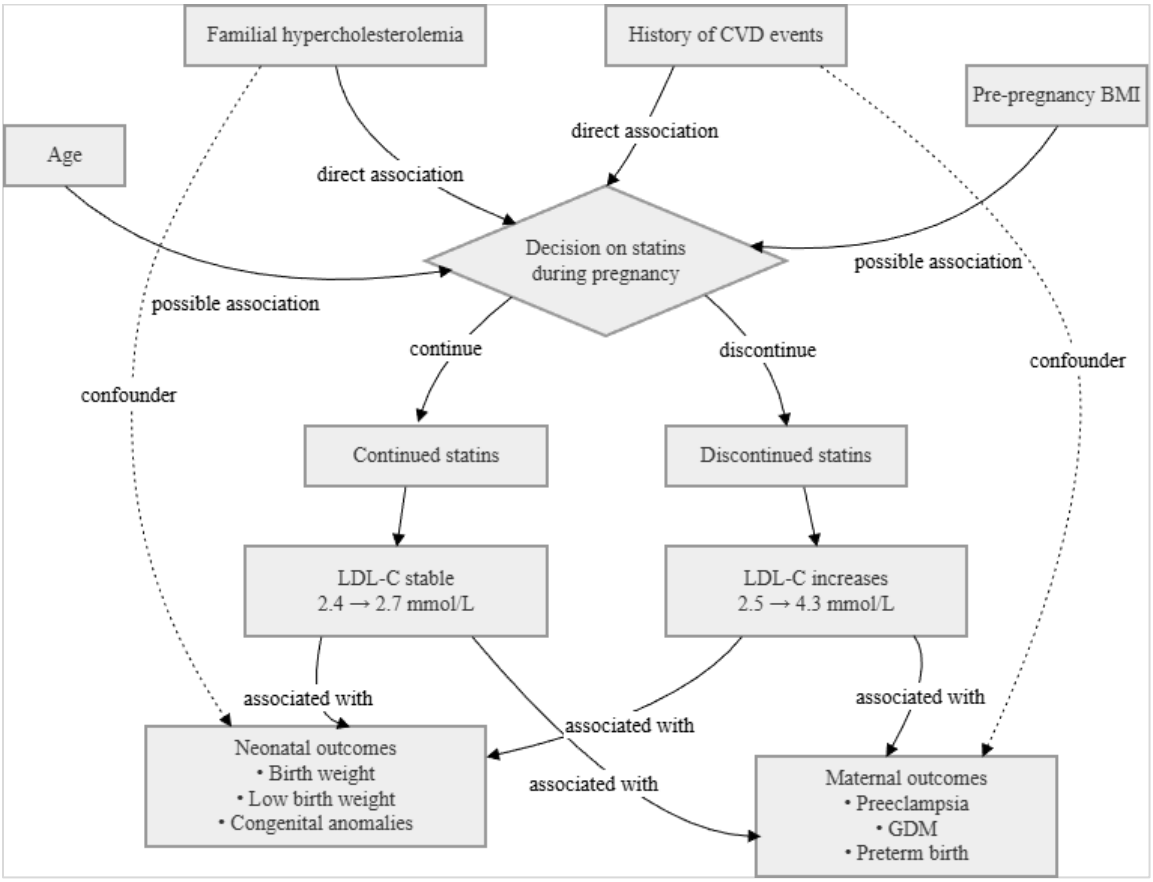

Figure 1. Directed acyclic graph (DAG) illustrating the relationships between baseline factors, the decision to continue or discontinue statin therapy during pregnancy, lipid profile, and maternal-neonatal outcomes.

Data were extracted from individual pregnancy and delivery records (form No. 111/u), birth histories (form No. 096/u), newborn records (form No. 097/u), and electronic databases. Data collection was performed by two teams of student researchers with subsequent cross-checking to minimize errors.

For each patient, we recorded age at delivery, pre-pregnancy body mass index, parity (primiparous or multiparous), clinical status before pregnancy (diagnosis for which statins were prescribed, including familial hypercholesterolemia, dyslipidemia due to obesity or metabolic syndrome, prior myocardial infarction or stroke, type 2 diabetes), arterial hypertension, and smoking status.

Regarding statin therapy, we collected drug name (atorvastatin, rosuvastatin, simvastatin, pravastatin, pitavastatin), daily dose, duration before pregnancy, whether therapy was continued or discontinued, and if continued, dosing regimen during pregnancy, and whether switching from a lipophilic to a hydrophilic statin occurred (Aksoy & Akaydin, 2024; Jegede, 2024; Singar, 2024).

Laboratory parameters included total cholesterol, LDL-C, HDL-C, and triglycerides, assessed at four time points: before pregnancy (3–12 months before conception), first trimester (8–12 weeks), second trimester (24–28 weeks), and third trimester (32–36

weeks). Postpartum lipid profiles (4–8 weeks after delivery) were also recorded when available.

Maternal outcomes included preeclampsia, gestational diabetes mellitus, preterm birth (<37 weeks), mode of delivery (spontaneous vaginal or cesarean section), and postpartum hemorrhage (blood loss >500 mL for vaginal delivery or >1000 mL for cesarean section) (World Health Organization, 2012). Neonatal outcomes included Apgar score at 1 and 5 minutes, birth weight, low birth weight (<2500 g), congenital anomalies (ICD-10 diagnosis), and admission to the neonatal intensive care unit (Harrison *et al*., 2021).

Data were analyzed using IBM SPSS Statistics 26.0 and R 4.2.0 (Sanchez *et al*., 2021; Ko *et al*., 2022). Normality was assessed with the Kolmogorov-Smirnov test. Since distribution was non-normal, quantitative data are presented as median (Q1; Q3) and categorical data as n (%). Groups were compared using the Mann-Whitney U test for quantitative variables and the χ^2 or Fisher's exact test for categorical variables. Lipid dynamics within each group across four time points were assessed using the Friedman test with post-hoc Wilcoxon and Bonferroni correction (α = 0.0083). Multivariable logistic regression was used to identify factors associated with statin continuation and neonatal outcomes, adjusting for confounders (age, BMI, parity, diabetes, and hypertension). Results are presented as aOR with 95% CI. All tests were two-sided with α = 0.05. Sample size calculation (80% power, α = 0.05) required 62 patients per group; we included 94 and 86.

Results and Discussion

Between January 1, 2021, and December 31, 2025, 180 women meeting the inclusion criteria were selected from perinatal centers in Vladikavkaz. Of these, 94 women (52.2%) continued statin therapy during pregnancy (Group 1), and 86 women (47.8%) discontinued statins upon pregnancy recognition (Group 2). The group size ratio was approximately 1.09:1.

Clinical and demographic characteristics. Baseline characteristics are shown in **Table 1.** Women in the continuation group were slightly older than those in the discontinuation group, but the difference was not statistically significant. Pre-pregnancy body mass index and the proportion of primiparous women were similar between groups.

The most common indication for statin prescription before pregnancy in the overall cohort was familial hypercholesterolemia, documented in 101 women (56.1%). Familial hypercholesterolemia was significantly more frequent in the continuation group than in the discontinuation group. A history of cardiovascular events (myocardial infarction or ischemic stroke) was also more frequent in the continuation group. Type 2 diabetes mellitus and pre-pregnancy arterial hypertension occurred with comparable frequency in both groups, although a trend toward higher rates was observed in the continuation group. The proportion of smokers was negligible in both groups.

Table 1. Clinical and demographic characteristics of patients

Characteristic	Group 1: Continuation (n=94)	Group 2: Discontinuation (n=86)	p
Age, years [Me (Q1; Q3)]	34 (30; 38)	32 (28; 36)	0.082
Pre-pregnancy BMI, kg/m² [Me (Q1; Q3)]	27.5 (24.2; 31.8)	26.8 (23.5; 30.4)	0.341
Primiparous, n (%)	51 (54.3)	49 (57.0)	0.752
Familial hypercholesterolemia, n (%)	61 (64.9)	40 (46.5)	0.014
History of cardiovascular events, n (%)	28 (29.8)	11 (12.8)	0.006
Type 2 diabetes mellitus, n (%)	19 (20.2)	12 (14.0)	0.267
Pre-pregnancy hypertension, n (%)	24 (25.5)	15 (17.4)	0.189
Smoking, n (%)	8 (8.5)	6 (7.0)	0.701

Statin therapy characteristics. In the continuation group, the most frequently prescribed statins were pravastatin (43 women, 45.7%) and rosuvastatin (31 women, 33.0%). Atorvastatin was taken by 15 women (16.0%), while simvastatin and pitavastatin were less common (3.2% and 2.1%, respectively). In 22 women (23.4%) in the continuation group, the drug was switched from a lipophilic statin (atorvastatin or simvastatin) to a hydrophilic statin (pravastatin or rosuvastatin) upon pregnancy recognition. In the discontinuation group, the most frequently prescribed statins before pregnancy were atorvastatin (37 women, 43.0%) and rosuvastatin (28 women, 32.6%).

Lipid profile dynamics. In the continuation group, median LDL-C remained stable throughout pregnancy: 2.4 mmol/L before pregnancy, 2.5 mmol/L in the first trimester, 2.6 mmol/L in the second trimester, and 2.7 mmol/L in the third trimester. Differences between time points were not statistically significant (p=0.324). In the discontinuation group, LDL-C increased significantly from 2.5 mmol/L before pregnancy to 3.2 mmol/L in the first trimester, 3.9 mmol/L in the second trimester, and 4.3 mmol/L in the third trimester (p<0.001). Pairwise comparisons revealed significant differences between baseline and the second and third trimesters, as well as between the first and third trimesters. Between-group differences were significant starting from the first trimester and increased thereafter.

Total cholesterol dynamics followed a similar pattern. In the continuation group, total cholesterol remained stable, whereas in the discontinuation group, it progressively increased from 4.6 mmol/L before pregnancy to 6.8 mmol/L in the third trimester. Triglycerides increased physiologically toward the third trimester in both groups, with higher absolute values in the discontinuation group. HDL-C levels did not differ between groups and remained stable throughout pregnancy **(Table 2).**

Table 2. Lipid profile dynamics

Parameter	Baseline	Trimester 1	Trimester 2	Trimester 3	p within	p between
LDL-C, mmol/L						
Group 1 (continuation)	2.4 (2.0;2.9)	2.5 (2.1;3.0)	2.6 (2.1;3.1)	2.7 (2.2;3.2)	0.324	
Group 2 (discontinuation)	2.5 (2.0;3.0)	3.2 (2.7;3.8)	3.9 (3.3;4.6)	4.3 (3.6;5.0)	<0.001	
p between groups	0.562	0.008	<0.001	<0.001		<0.001
Total cholesterol, mmol/L						
Group 1 (continuation)	4.5 (3.9;5.1)	4.6 (4.0;5.2)	4.8 (4.1;5.4)	4.9 (4.2;5.5)	0.187	
Group 2 (discontinuation)	4.6 (4.0;5.2)	5.4 (4.8;6.1)	6.2 (5.5;7.0)	6.8 (6.0;7.6)	<0.001	
p between groups	0.438	0.012	<0.001	<0.001		<0.001
Triglycerides, mmol/L						
Group 1 (continuation)	1.4 (1.1;1.8)	1.6 (1.2;2.0)	2.1 (1.7;2.6)	2.6 (2.1;3.2)	<0.001	
Group 2 (discontinuation)	1.4 (1.1;1.9)	1.8 (1.4;2.3)	2.4 (1.9;3.0)	3.0 (2.4;3.7)	<0.001	
p between groups	0.891	0.234	0.078	0.042		0.187

Note: Data are presented as median (Q1; Q3). p within — Friedman test; p between — Mann-Whitney U test for each time point.

Maternal outcomes. Maternal outcomes are shown in **Table 3.** The frequency of preeclampsia (8.5% vs. 7.0%), gestational diabetes mellitus (12.8% vs. 10.5%), cesarean section (28.7% vs. 26.7%), and postpartum hemorrhage (4.3% vs. 3.5%) did not differ between groups. Preterm birth (<37 weeks) occurred in 9.6% of women in the continuation group and 5.8% in the discontinuation group, but this difference was not statistically significant (p=0.347).

Table 3. Maternal outcomes

Outcome	Group 1: continuation (n=94)	Group 2: discontinuation (n=86)	p
Preeclampsia, n (%)	8 (8.5)	6 (7.0)	0.701
Gestational diabetes mellitus, n (%)	12 (12.8)	9 (10.5)	0.631
Preterm birth (<37 weeks), n (%)	9 (9.6)	5 (5.8)	0.347
Cesarean section, n (%)	27 (28.7)	23 (26.7)	0.764
Postpartum hemorrhage, n (%)	4 (4.3)	3 (3.5)	0.789

Neonatal outcomes. Neonatal outcomes are shown in **Table 4.** Apgar scores at 1 and 5 minutes did not differ between groups. Median birth weight was significantly lower in the continuation group (3180 g vs. 3350 g, p=0.031). Low birth weight (<2500 g) occurred in 9.6% of the continuation group and 3.5% of the discontinuation group (p=0.096). The frequency of congenital anomalies was comparable between groups (1.1% vs. 1.2%). NICU admission rates did not differ (7.4% vs. 5.8%, p=0.662).

Table 4. Neonatal outcomes

Outcome	Group 1: continuation (n=94)	Group 2: discontinuation (n=86)	p
Apgar at 1 minute [Me (Q1; Q3)]	8 (7; 8)	8 (7; 8)	0.652
Apgar at 5 minutes [Me (Q1; Q3)]	9 (8; 9)	9 (8; 9)	0.721
Birth weight, g [Me (Q1; Q3)]	3180 (2950; 3420)	3350 (3100; 3580)	0.031
Low birth weight (<2500 g), n (%)	9 (9.6)	3 (3.5)	0.096
Congenital anomalies, n (%)	1 (1.1)	1 (1.2)	0.987
NICU admission, n (%)	7 (7.4)	5 (5.8)	0.662

Logistic regression analysis. Multivariable logistic regression identified familial hypercholesterolemia and a history of cardiovascular events as independent predictors of statin continuation during pregnancy. Baseline LDL-C, age, BMI, and pre-pregnancy hypertension showed no significant association. After adjusting for confounders (maternal age, BMI, parity, diabetes, and hypertension), statin continuation was associated with lower birth weight but not with low birth weight, congenital anomalies, or NICU admission.

This retrospective cohort study of 180 women who took statins before pregnancy provides three key findings. First, statin discontinuation was associated with a progressive increase in LDL-C during pregnancy (from 2.5 to 4.3 mmol/L), while continuation kept LDL-C stable (2.4–2.7 mmol/L). Second, maternal complication rates (preeclampsia, gestational diabetes, preterm birth) did not differ between groups. Third, statin continuation was associated with significantly lower birth weight (3180 g vs. 3350 g, p = 0.031) without an increase in congenital anomalies (Aschenbrenner, 2021; Vahedian-Azimi *et al*., 2021).

Lipid Profile Dynamics

The rise in LDL-C in the discontinuation group is consistent with physiological lipid changes during pregnancy, driven by increased hepatic lipogenesis and hormonal shifts (Zhu *et al*., 2022). This mechanism ensures fetal cholesterol supply for myelination, steroid synthesis, and cell membrane formation (Firatligil *et al*., 2025). In the continuation group, stable LDL-C levels demonstrate that statins maintain their pharmacological activity during pregnancy despite changes in pharmacokinetics (increased volume of distribution, higher clearance, lower albumin levels) (Hirsch *et al*., 2022). Although LDL-C levels in the discontinuation group exceeded target values for high-risk patients, large nationwide cohort studies from 2025–2026 have shown that short-term statin discontinuation during pregnancy (9–10 months) is not associated with increased maternal cardiovascular events, even in very high-risk subgroups (familial hypercholesterolemia, documented atherosclerotic disease) (Lewek *et al*., 2024). The protective effect of prior long-term statin therapy may persist for months after discontinuation (Cuchel *et al*., 2023).

Predictors of Continuation

In our study, 52.2% of women continued statins during pregnancy. Multivariable logistic regression identified familial hypercholesterolemia and a history of cardiovascular events as independent predictors of continuation, consistent with guidelines limiting continuation to very high-risk cases (Lumsden & Pagidipati, 2022). Notably, 23.4% of women in the continuation group switched from a lipophilic to a hydrophilic statin (pravastatin or rosuvastatin), reflecting clinical adoption of evidence that hydrophilic statins are preferred during pregnancy due to P-glycoprotein-mediated placental efflux, with fetal pravastatin levels only about 30% of maternal levels (Christensen *et al*., 2023; Poornima *et al*., 2023).

Preeclampsia and Maternal Outcomes

Preeclampsia rates did not differ between groups (8.5% vs. 7.0%, $p = 0.701$). This finding is consistent with a 2025 meta-analysis of 11 studies (10,482 women) which reported a pooled relative risk of 0.78 (95% CI: 0.33–1.83, $p = 0.57$) (Lewek & Banach, 2022). Although the difference was not statistically significant, some subgroup analyses have suggested that early statin initiation (before 20 weeks of gestation) might be associated with a trend toward lower preeclampsia risk, warranting further investigation (Ramanathan *et al*., 2026). Other maternal outcomes (gestational diabetes, preterm birth, cesarean section, postpartum hemorrhage) also showed no differences, possibly due to true lack of effect or insufficient statistical power (Nielsen *et al*., 2025).

Neonatal Outcomes and Fetal Safety

Statin continuation was associated with significantly lower birth weight (3180 g vs. 3350 g, $p = 0.031$) and a trend toward higher low birth weight (<2500 g: 9.6% vs. 3.5%, $p = 0.096$). This aligns with studies suggesting that cholesterol synthesis inhibition in the fetus may limit growth, as cholesterol is critical for myelination, membrane formation, and steroid synthesis (Nabizadeh *et al*., 2023; Firatligil *et al*., 2025). However, NICU admission rates and Apgar scores did not differ, suggesting that the effect on birth weight is not clinically significant (Mauricio & Khera, 2022). Congenital anomaly rates were low and comparable between groups (1.1% vs. 1.2%), confirming observational studies that found no significant teratogenic risk (Aschenbrenner, 2021; Vahedian-Azimi *et al*., 2021). This evidence led the FDA to remove category X labeling from all statins in July 2021 (Poornima *et al*., 2023).

Gender Differences

Women are less likely than men to achieve LDL-C targets, experience delayed treatment initiation, and have higher discontinuation rates due to biological and systemic factors (Zamora *et al*., 2023; Iatan *et al*., 2024). Pregnancy adds further complexity, but our data show that in real-world practice, a significant proportion of high-risk women continue statins during pregnancy, reflecting a shift toward individualized risk-benefit assessment (Poornima *et al*., 2023; Patel *et al*., 2025).

Limitations

This study has several limitations: retrospective design, relatively small sample size (180 patients) limiting power for rare outcomes, lack of control for potential confounders (diet, physical activity, other medications, gestational BMI), absence of postpartum lipid data in some patients, no long-term follow-up of children, and limited external validity (two centers in southern Russia) (Stürzebecher & Laufs, 2026).

Practical Recommendations

For most women with moderate cardiovascular risk, statin discontinuation upon pregnancy recognition with resumption after lactation is reasonable (Yang *et al*., 2022; Poornima *et al*., 2023). For women at very high risk (recent cardiovascular events, severe familial hypercholesterolemia with LDL-C >13 mmol/L), continuation with a hydrophilic statin (pravastatin) at the minimum effective dose may be considered, along with mandatory fetal growth monitoring (Christensen *et al*., 2023; Lewek *et al*., 2024). Future prospective studies and registries are needed to assess long-term outcomes of statin-exposed children and to determine the role of statins in preeclampsia prevention (Lewek & Banach, 2022; Akbar *et al*., 2024).

Conclusion

This retrospective cohort study of 180 women who took statins before pregnancy and delivered at perinatal centers in Vladikavkaz between 2021 and 2025 compared lipid profile dynamics and maternal and neonatal outcomes between those who continued or discontinued statin therapy during pregnancy. Statin discontinuation was associated with a marked progressive increase in LDL cholesterol, reaching 4.3 mmol/L by the third trimester, while continuation kept LDL cholesterol stable within the range of 2.4–2.7 mmol/L. The decision to continue therapy was made by 52.2% of women and was independently associated with familial hypercholesterolemia and a history of cardiovascular events. Maternal complication rates (preeclampsia, gestational diabetes, preterm birth) did not differ between groups. Statin continuation

was associated with significantly lower neonatal birth weight (3180 g vs. 3350 g, p=0.031) and a trend toward higher low birth weight (9.6% vs. 3.5%, p=0.096), while congenital anomaly rates (1.1% vs. 1.2%), Apgar scores, and NICU admission did not differ. For most women with moderate cardiovascular risk, statin discontinuation upon pregnancy recognition with resumption after lactation is reasonable. For women at very high risk (recent cardiovascular events, severe familial hypercholesterolemia), continuation with hydrophilic statins (pravastatin) at the minimum effective dose may be considered with mandatory fetal growth monitoring. The main limitations of this study are its retrospective design, relatively small sample size, and lack of long-term child outcome data. Further prospective studies are needed to assess the long-term effects of in utero statin exposure on neurocognitive and metabolic development of offspring.

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Conflict of interest: None

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Ethics statement: This retrospective cohort study was conducted in accordance with the ethical standards of the institutional research committee of North Ossetian State Medical Academy (Vladikavkaz, Republic of North Ossetia-Alania, Russia) and with the principles of the Declaration of Helsinki (2013 revision). Due to the retrospective nature of the study and the use of anonymized data from medical records (individual pregnancy and delivery records, birth histories, newborn records, and electronic databases), informed consent was not required. All patient data were processed in compliance with applicable data protection regulations. Patient confidentiality was maintained throughout the study by anonymizing all clinical data, with removal of all personal identifiers prior to analysis and publication.

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