The aim of the article is to review systematically current researches investigating the relationship between intrauterine exposure to antidepressants and neonatal hypoglycemia. This paper included studies published in electronic databases from January 2005 to July 2020. The searched keywords were as follows: antidepressants, pregnancy, selective serotonin reuptake inhibitors (SSRIs), citalopram, fluoxetine, paroxetine, escitalopram, sertraline, fluvoxamine, selective serotonin-norepinephrine reuptake inhibitors (SNRIs), venlafaxine, tricyclic antidepressants (TCAs), neonatal outcomes, neonatal hypoglycemia, imipramine, clomipramine, amitriptyline, bupropion, trazodone, and mirtazapine. This review examined 10 relevant studies. The odds ratio/risk ratio reported in the studies were 1.33-1.73 for any antidepressant, 1.30-1.35 for SSRI, 1.42-2.11 for SNRI, and 2.07 for TCAs. The risk of neonatal hypoglycemia in infants exposed to maternal TCAs appears to be slightly higher compared to infants exposed to maternal SSRIs. Data from current studies consistently show that exposure to maternal antidepressants during pregnancy may be related to increased risk of neonatal hypoglycemia in infants.

Keywords: Antidepressive agents, hypoglycemia, pregnancy, therapeutics

Introduction

Hypoglycemia, a prime metabolic issue in newborns, is defined as a blood glucose level less than 47 mg/dL. It can be observed in up to 10% of healthy term newborns. Although neonatal hypoglycemia is mostly transient and asymptomatic and represents an adaptation to postnatal life, it may progress to coma and death if it becomes severe or prolonged.1,2 Studies have demonstrated that neonatal hypoglycemia can lead to neurodevelopmental impairment and motor developmental delay at childhood.3,4 Maternal, fetal and neonatal factors can contribute to neonatal hypoglycemia. Maternal diabetes mellitus, prematurity, intrauterine growth issues, perinatal hypoxia, congenital heart disease and maternal medications are some of the risk factors for neonatal hypoglycemia.1,5

Molenaar et al6 have showed that the use of antidepressants during pregnancy is frequent and varies significantly between communities. Consequently, a growing body of researches has evaluated the safety of maternal use of antidepressants during pregnancy in the last 2 decades. Evidence suggesting an elevated risk of neonatal issues such as prematurity, low birth weight, persistent pulmonary hypertension, neonatal seizures, and poor neonatal adaptation syndrome7-12 have led to increased concerns on treatment with antidepressants of pregnant patients. Hypoglycemia is considered to be among neonatal morbidities, neonatal complications, or symptoms of neonatal adaptation syndrome.13-15 However, compared to other perinatal conditions, such as respiratory distress, the requirement of neonatal care, and Apgar score, the risk of neonatal hypoglycemia in newborns of a mother receiving antidepressant medication has been less frequently investigated. Therefore, the goal of the current review was to systematically assess whether there is any connection between intrauterine exposure to antidepressants and neonatal hypoglycemia in newborns based on data from recently published studies.
Methods
This systematic review based on the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines and checklist. The review included English language papers published in electronic databases including PubMed, Web of Science, PsycInfo from January 2005 to July 2020. The following keywords for literature search were used: pregnancy, antidepressants, selective serotonin reuptake inhibitors (SSRIs), citalopram, fluoxetine, paroxetine, escitalopram, sertraline, fluvoxamine, selective serotonin-norepinephrine reuptake inhibitors (SNRIs), venlafaxine, tricyclic antidepressants (TCAs), neonatal outcomes, neonatal hypoglycemia, imipramine, clomipramine, amitriptyline, bupropion, trazodone, and mirtazapine. Additionally, the citations in the papers were examined to refer to other relevant studies.

The studies included in this article had the following criteria: (1) publication in a peer-reviewed journal, (2) clearly reported results including odds ratio (OR), hazard ratio, risk ratio (RR), or prevalence rate of neonatal hypoglycemia, and (3) inclusion of infants exposed and unexposed to antidepressants. This review excluded comments on published studies, editorials, letters to the editor, reviews, meta-analyses, animal studies, and case reports. After screening the literature with the search words indicated above, non-duplicated titles were identified. Abstracts of these titles were examined for the exclusion criteria and relevance to the topic of this review. The relevant full texts were provided and reviewed to determine whether they met their criteria for inclusion. Figure 1 presents the flow diagram of studies included in this review.

Results
Table 1 shows the general characteristics and results of the current 10 studies. Four of the 10 studies were based on Swedish Medical

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**MAIN POINTS**
- Antidepressants are frequently used to treatment of depression and anxiety disorders in pregnant women.
- Antidepressants seem to be associated with higher risk of neonatal hypoglycemia.
- The results of the current studies should be evaluated with caution owing to the reported methodological limitations and small sample sizes in prospective comparative studies.
Table 1. Characteristics of Studies Included in this Review

| Study                        | Design/Sample characteristics                                   | Main results                                                                 | Adjusted confounders                                                                 | Major limitations                                                                 |
|------------------------------|-----------------------------------------------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| Lennestål and Källén, 2007   | Swedish Medical Birth Registry Database                         | Prevalence of hypoglycemia: SNRI/NRI: 4.64%                                   | Maternal age, parity, smoking, previous miscarriages, and body mass index             | Did not exclude potential effects of other psychotropics used concurrently        |
|                              | Sample                                                          | SNRI: 3.65%                                                                   |                                                                                      | Unclear data on duration of actual use of antidepressants                         |
|                              | Total population: 860 215                                      | Adjusted RR (95% CI)                                                          |                                                                                      | No data on psychiatric diagnoses                                                  |
|                              | SNRI/NRI (mianserin, mirtazapine, reboxetine, or venlafaxine)  | SNRI/NRI, early exposure: 1.42 (1.00-1.99) (S)                                |                                                                                      | No data on daily dose of antidepressants used by the patients                    |
|                              | 732                                                             | SNRI/NRI, late exposure: 2.11 (1.01-3.89) (S)                                 |                                                                                      | Did not exclude potential effects of preterm birth                               |
|                              | SSRI: 6481                                                      | SSRI, early exposure: 1.17 (1.02-1.33) (S)                                    |                                                                                      |                                                                                  |
|                              |                                                                  | SSRI, late exposure: 1.32 (1.05-1.68) (S)                                     |                                                                                      |                                                                                  |
| Källén, 2004                  | Prospectively recorded data from Swedish Medical Birth Registry Database | Prevalence of hypoglycemia: Antidepressant: 4.91%                            | Maternal age, parity, and smoking                                                     | Did not exclude potential effects of other psychotropics used concurrently        |
|                              | Sample                                                          | TCA: 5.83%                                                                   |                                                                                      | Unclear data on duration of actual use of antidepressants                         |
|                              | Total population: 581 787                                      | SSR: 4.30%                                                                   |                                                                                      | No data on psychiatric diagnoses                                                  |
|                              | Antidepressant: 997                                            | Total population: 3.04%                                                       |                                                                                      | No data on daily dose of antidepressants used by the patients                    |
|                              | TCA: 395                                                        | Adjusted OR (95% CI), overall                                                |                                                                                      | Did not exclude potential effects of preterm birth and low birth weight           |
|                              | SSRI: 558                                                       | Antidepressant: 1.62 (1.22-2.16) (S)                                          |                                                                                      |                                                                                  |
|                              | Others: 63                                                     | TCA: 2.07 (1.36-3.13) (S)                                                    |                                                                                      |                                                                                  |
|                              |                                                                  | SSR: 1.35 (0.90-2.03) (S)                                                     |                                                                                      |                                                                                  |
|                              |                                                                  | Adjusted OR (95% CI), late exposure                                          |                                                                                      |                                                                                  |
|                              |                                                                  | Antidepressant: 1.49 (1.00-2.23) (S)                                          |                                                                                      |                                                                                  |
| Jordan et al, 2008           | Retrospective cohort study                                     | Prevalence of hypoglycemia: SSRI and venlafaxine: 0%                         | Both groups have similar demographic features and psychiatric diagnoses               | Small sample size                                                                 |
|                              | Sample                                                          | Control: 5.08%                                                                |                                                                                      | Unclear effects of severity of psychiatric diagnoses                              |
|                              | SSRI and venlafaxine: 49                                       |                                                                  |                                                                                      |                                                                                  |
|                              | Control: 59                                                    |                                                                  |                                                                                      |                                                                                  |
| Reis and Källén, 2010         | Data from Swedish Medical Birth Register Database               | Adjusted OR (95% CI)                                                         | Maternal age, parity, smoking, and body mass index                                   | Unclear data on duration of actual use of antidepressants                         |
|                              | Sample                                                          | Early exposure: 1.33 (1.22-1.45) (S)                                          |                                                                                      | No data on psychiatric diagnoses                                                  |
|                              | Antidepressant: 15 017                                         | Late exposure: 1.43 (1.31-1.65) (S)                                           |                                                                                      | No data on daily dose of antidepressants used by the patients                    |
| Engelstad et al, 2014         | Retrospective study                                            | Prevalence of hypoglycemia: Depression: 2.75%                                | Maternal age, parity, smoking, and body mass index                                   | Did not exclude potential effects of preterm birth and low birth weight           |
|                              | Sample                                                          | Depression: 3.96%                                                            |                                                                                      |                                                                                  |
|                              | Depression: 254                                                | No SSRI: 1.56%                                                                |                                                                                      |                                                                                  |
|                              | SSRI: 126                                                      | Control: 1.80%                                                                |                                                                                      |                                                                                  |
|                              | No SSRI: 128                                                   | Statistical comparisons                                                      |                                                                                      |                                                                                  |
|                              | Control: 222                                                   | Depression vs control NS                                                      |                                                                                      |                                                                                  |
|                              |                                                                  | SSRI vs no SSRI: NS                                                           |                                                                                      |                                                                                  |

(Continued)
Birth Databases.13,15,17,18 The remaining 6 studies had a retrospective or prospective cohort design.14,18-22 Shah et al21 specifically examined the risk of neonatal hypoglycemia. The other authors reported the risk of several neonatal outcomes. Most studies evaluated the effects of SSRIs15,17,18,20,23 or any antidepressant.13,14,18,21 Single studies were available for patients who received TCAs,18 SNRI,17 SSRI and venlafaxine,19 no SSRIs,20 and individual SSRIs.14,22

It was reported that neonatal hypoglycemia was observed in 0-5.08% of non-exposed controls.15,18-23 In contrast, this rate was 4.91-19.0% in infants exposed to any antidepressant,14,18,21 3.50-5.0% in infants exposed to SSRIs,15,17,18,20,23 4.65% in infants exposed to SNRIs,17 and 5.85% in infants exposed to TCAs.18 Forsberg et al14 reported the highest prevalence of neonatal hypoglycemia ranging from 10.39% for citalopram to 35.29% for fluoxetine. The prevalence rate for any antidepressant in their study was about 3-fold higher than reported in other studies. Forsberg et al14 also reported that while the prevalence rate of neonatal hypoglycemia in newborns exposed to fluoxetine was significantly higher compared to newborns exposed to citalopram, the prevalences with citalopram, sertraline, or other antidepressants were similar. In addition, Engelstad et al20 reported that the difference in the prevalence rate of neonatal hypoglycemia in infants exposed to SSRIs and non-SSRIs did not reach statistical significance.

When compared to controls, the reported OR/RR was 1.33-1.73 for any antidepressant,13,14,18,21 1.30-1.35 for SSRIs15,17,18 1.42-2.11 for SNRI,17 and 2.07 for TCAs.18 The OR/RR reached statistical significance in all of the studies except Shah et al21. The latter authors reported a RR of 1.73 for any antidepressant versus the control group

Table 1. Characteristics of Studies Included in this Review (Continued)

| Study                      | Design/Sample characteristics | Main results                                      | Adjusted confounders | Major limitations                      |
|----------------------------|-------------------------------|--------------------------------------------------|----------------------|----------------------------------------|
| Shah et al, 202021         | Prospective comparative cohort study | Prevalence of hypoglycemia Antidepressant: 6.78% Unexposed: 3.27% | Maternal age, gestational age, smoking, and alcohol and substance use | Small sample size No data on psychiatric diagnoses |
| Nörby et al, 201615        | Swedish Medical Birth Register and Prescribed Drug Register Database | Prevalence of hypoglycemia SSR: 3.95% No antidepressant: 2.42% | Maternal age, primiparity, smoking, other neurotropic drugs, body mass index, cesarean delivery, gestational age, and birth weight | Unclear data on duration of actual use of antidepressants No data on psychiatric diagnoses No data on a daily dose of antidepressants used by the patients |
| Costei et al, 200222       | Prospective, controlled cohort study | Prevalence of hypoglycemia Paroxetine Late exposure: 1.81 Early exposure: 0 Control: 0 | - | Small sample size Unclear effects of preterm birth and birth weight No data on psychiatric diagnoses Unclear effects of daily dose |
| Forsberg et al, 201414     | Retrospective cohort study     | Prevalence of hypoglycemia Antidepressant: 19.09% Citalopram: 10.39% Sertraline: 19.73% Fluoxetine: 35.29% Others: 21.21% | Maternal age, gestational age, gender of the baby | Small sample size No data on psychiatric disorders Lack of control group with unexposed infants |
| Levinson-Castiel et al, 200623 | Cohort study | Prevalence of hypoglycemia SSR: 5.00% Control: 0 | Other medications, alcohol or substance use, congenital anomalies | Small sample size No data on psychiatric disorders Unclear effects of daily dose |

NS, non-significant; SRI, serotonin reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; SNRI, serotonin-noradrenaline reuptake inhibitor; NRI, noradrenaline reuptake inhibitor; TCA, tricyclic antidepressants; OR, odds ratio; RR, risk ratio.
According to a study by Källén, the risk of neonatal hypoglycemia among antidepressant users was associated with a higher risk compared to others and SNRIs. It is unclear which antidepressant group or individual antidepressant was significantly increased in infants of women using primarily TCAs but also SNRIs and SSRIs.

Three studies analyzed the relationship between the risk of hypoglycemia in newborns and the timing of antidepressant exposure during pregnancy. Two Swedish Medical Birth Database studies suggested that antidepressant exposure at both early and late gestational periods was significantly related to elevated neonatal hypoglycemia. Although a statistical comparison was not reported, the ORs were higher with late exposure compared to early exposure. In addition, a prospective controlled cohort study reported that the prevalence rates of neonatal hypoglycemia in infants exposed to paroxetine in early and late periods of pregnancy were 0% and 1.81%, respectively.

None of the available studies included any adjusted analyses for maternal psychiatric disorders such as depression and anxiety disorders. In a retrospective cohort study, antidepressant and control groups had similar characteristics for maternal psychiatric diagnoses, and the reported prevalence rates for neonatal hypoglycemia were 0% in the SSRI/venlafaxine group and 5.08% in the control group. Additionally, Engelstad et al reported that the difference in the prevalence rate of neonatal hypoglycemia in the depression (2.75%) and the control (1.80%) groups was not statistically significant.

Discussion

The prevalence rates of neonatal hypoglycemia in infants of antidepressant users in the studies included in this systematic review were mostly between 3 and 6%. The available data on the risk of neonatal hypoglycemia with maternal use of antidepressants is consistent, with an up to 73% elevated risk compared to the controls. When the reported prevalence rates in the unexposed infants are considered, the absolute risk appears to be 1-3%.

The most commonly prescribed antidepressants in pregnant women are SSRIs. Therefore, more data on antenatal exposure to SSRIs are available and consistently suggest an increased risk of neonatal hypoglycemia with these antidepressant groups. Similarly, limited available data demonstrate this significantly increased risk with TCAs and SNRIs. It is unclear which antidepressant group or individual antidepressant is associated with higher risk compared to others. According to a study by Källén, the risk of neonatal hypoglycemia was slightly greater in infants of TCA users compared to SSRI users. Engelstad et al reported that infants exposed to SSRIs and other antidepressants had similar risk profiles. Although fluoxetine specifically appeared to have the highest risk among SSRIs for neonatal hypoglycemia, this data derived from a single study and should be confirmed with further studies.

Two important factors evaluating risks on neonatal outcomes are the role of timing of antidepressant exposure and underlying maternal psychopathology. The Swedish Medical Birth Register Database studies suggested that exposure during both early pregnancy (representing the first and second trimester) and late pregnancy (representing the third trimester) were risky for neonatal hypoglycemia.

Discussion

As shown in Table 1, the current studies have several major methodological limitations. The available data were derived from either electronic birth registry databases or retrospective or prospective studies with small sample sizes. Indeed, prospective observational comparative studies with large sample sizes would provide stronger data; however, the execution of such a study design in pregnant patients is challenging. Although birth register database studies present enough data for powerful statistical analyses, they have considerable limitations such as lack of information on the duration of actual use of antidepressants, the daily dose of antidepressants prescribed, and clinical indication for the use of antidepressants (psychiatric and non-psychiatric). In addition, 4 birth registry database studies included in this review used data from only one country; therefore, the results may be specific to the population of that country. Most studies did not examine possible effects of confounders such as concurrent use of psychotropic medications other than antidepressants, preterm birth, and birth weight. Many patients with severe depression and anxiety disorders require combinations of psychotropic drugs. In addition, the use of antidepressants in the gestational period may negatively affect gestational age and birth weight in newborns. Lack of data on the possible effects of maternal psychiatric conditions and their severity is another important limitation. Finally, most studies did not examine the etiology underlying neonatal hypoglycemia, clinical features (clinically symptomatic or asymptomatic), and severity or prognosis in infants with hypoglycemia. It is expected that similar to other poor neonatal adaptation signs, neonatal hypoglycemia due to antidepressant exposure in utero may be generally mild and transient; however, this topic should be investigated by future studies.

In conclusion, the current systematic review suggests that pregnant women who receive antidepressant treatment have a greater likelihood of their infants developing neonatal hypoglycemia compared to pregnant women who do not use these medications. However, the study results should be evaluated with caution owing to the reported methodological limitations and small sample sizes in prospective comparative studies. Future studies should be designed by considering the limitations noted in this review. Large-scale multicenter prospective observational studies including comparative groups with similar characteristics for gestational age, birth weight, concurrently used medications, and maternal psychiatric diagnoses are required to reach definitive conclusions.
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