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Determining the Severity of Neonatal Abstinence Syndrome Among Newborns Exposed to Selective Serotonin Reuptake Inhibitors and Serotonin and Norepinephrine Reuptake Inhibitors in Utero: A Protocol for a Systematic Review and Meta-Analysis

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Abstract

Introduction: Depression among expectant adults is increasing. This may contribute to newborns experiencing withdrawal symptoms following *in utero* exposure to antidepressants. Selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs) are the most commonly prescribed classes of antidepressants. Newborns with Neonatal Abstinence Syndrome (NAS) following fetal opioid exposure receive systematic screening and pharmacological treatment based on results from the Finnegan Neonatal Abstinence Scoring System (FNASS). In contrast, newborns exposed to SSRIs/SNRIs may not receive routine screening, thus SSRI-/SNRI-induced NAS may go undiagnosed and untreated, due to the lack of awareness of the consequences of SSRI-SNRI exposure *in utero.*

Methods: We will search electronic databases (Ovid MEDLINE, Ovid Embase, The Cochrane Central Register of Controlled Trials, ClinicalTrials.gov, and grey literature) from inception to July 2021 for relevant articles. Two independent reviewers will eliminate duplicate articles, screen to select relevant articles, extract quantitative data pertaining to FNASS scores and assess for risks of biases.

Results: Upon conducting this systematic review, we hypothesize the results will support our objective of determining the prevalence of NAS among neonates exposed to SSRIs/SNRIs *in utero*. Majority of neonates diagnosed with moderate to severe opioid-induced NAS receive systematic screening and pharmacological treatment. In contrast, neonates exposed to SSRIs/SNRIs may not be systematically screened, and so go on to be untreated. This is concerning considering the potential adverse effects related to untreated NAS

Discussion: We plan to use the results of our meta-analysis to yield a summary of average FNASS scores in neonates exposed to SSRIs or SNRIs *in utero* (primary outcome). In addition, we aim to compare the resulting FNASS summary score against the proportion of neonates who received pharmacological treatment for NAS (secondary outcome).

Conclusion: In conducting our proposed systematic review, we aim to determine the severity of SSRI-/SNRI-induced NAS using the FNASS scoring tool, the prevalence of newborns who receive pharmacological treatment for this condition, and to emphasize the development of standardized evidence-based guidelines for the treatment of newborns with SSRI-/SNRI-induced NAS.

Keywords: neonatal abstinence syndrome; postnatal withdrawal; Finnegan neonatal abstinence scoring system; selective serotonin reuptake inhibitors; serotonin and norepinephrine reuptake inhibitors

Introduction

Neonatal Abstinence Syndrome (NAS) refers to the postnatal withdrawal symptoms observed among newborns following *in utero* exposure to maternal drugs [1]. While traditional definitions refer to withdrawal following antenatal exposure to opioids, evidence indicates that newborns exposed to other drugs *in utero* may also exhibit withdrawal symptoms [1]. One category of these drugs is antidepressants, specifically selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs) [2,3]. SSRIs and SNRIs limit the reuptake of the neurotransmitters serotonin and norepinephrine, respectively, by the presynaptic cell, increasing their availability at the postsynaptic cell (4,5). SSRIs and SNRIs are among the most common classes of prescribed antidepressants [6].

Newborns exposed to SSRIs and SNRIs *in utero* may exhibit a range of NAS symptoms that impact the central and autonomic nervous systems and the respiratory and gastrointestinal systems [1]. These symptoms can include

tremors, increased muscle tone, seizures, temperature instability, tachypnea, and poor feeding, among others [2]. The degree of severity of NAS is typically classified using the Finnegan Neonatal Abstinence Scoring System (FNASS) [7] with FNASS scores between 0 and 3 considered normal; scores between 4 and 7 considered mild; and a score of 8 or above considered severe NAS, requiring pharmacological treatment [8]. The literature regarding the prevalence of SSRI- and SNRI-induced NAS is limited. However, one study found that the occurrence of SSRI-induced NAS was approximately 30% [8].

The established short-term complications of *in utero* exposure to SSRIs and SNRIs include detrimental effects on the central and autonomic nervous systems and the respiratory and gastrointestinal systems [2]. There is also an increased occurrence of neonatal intensive care unit admission and prolonged newborn hospitalization associated with NAS [1,9-12]. In addition, there may be long-term effects of SSRI- and SNRI-induced NAS. Among newborns with opioid-induced NAS, long-term complications include poor neurocognitive and physical development that persists until adolescence [13]. Research on the long-term effects of SSRI- and SNRI-induced NAS is limited. However, one study identified a higher risk of social-behaviour abnormalities among children exposed to SSRIs *in utero* when compared to the background population [14].

Twenty-seven to 91% of newborns receive pharmacological treatment for moderate to severe opioid-induced NAS [15], as untreated NAS can result in significant morbidity and mortality [16]. However, newborns exposed to SSRIs or SNRIs may not be routinely screened, diagnosed, or treated. Considering the consequences of untreated opioid-induced NAS [16], concerns have risen regarding the outcomes of newborns with SSRI- or SNRI-induced NAS who may receive neither the required screening nor treatment.

The increasing prevalence of depression in pregnancy [17] and recommendations against the abrupt discontinuation of antidepressants in pregnancy [18-20] may result in more newborns with SSRI- and SNRI-induced NAS. Given that newborns are unlikely to receive routine screening for NAS due to the gaps in research on SSRI-SNRI consequences in infants, SSRI- and SNRI-induced NAS is at risk of being undiagnosed, untreated, or wrongly attributed to other factors. Considering the consequences of untreated opioid-induced NAS [16], it is necessary to characterize the data regarding the occurrence, severity, and treatment of NAS in newborns exposed to SSRIs and SNRIs in order to prevent unneeded morbidity and mortality in this vulnerable population.

Therefore, our objective is to conduct a systematic review to determine the severity of SSRI- and SNRI-induced NAS. We also aim to identify the proportion of newborns who receive pharmacological treatment for SSRI and SNRI-induced NAS.

Table 1. PEO Framework

Population	The population of interest is newborns from birth up to 28 days of age.
Exposure	The exposure is maternal use of SSRIs or SNRIs at any dose and for any duration during pregnancy.
Outcome	The primary outcome is FNASS score, with scores of 0 to 3 considered mild, scores of 4 to 7 considered moderate, and scores of 8 and above considered severe. The secondary outcome is any pharmacological treatment of NAS, including first-line medications and adjunctive agents.

Methods

The reporting of this systematic review protocol was in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) [21]. The conduct and reporting of the full systematic review will be directed by the Joanna Briggs Institute Manual for Evidence Synthesis [22] and the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) [23] guidelines. This protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (awaiting registration number).

Information Sources and Search Strategy

We plan to search the electronic databases Ovid MEDLINE, Ovid Embase, The Cochrane Central Register of Controlled Trials (CENTRAL), and ClinicalTrials.gov from inception to July 2021. We will also search for grey literature, hand search the reference lists of relevant studies, and contact study authors in pursuit of additional eligible studies. In order to access all available, relevant studies, we will not employ any limitations, such as language, year or study design at this stage.

Our search strategy will be developed in Ovid MEDLINE in consultation with a professional librarian and peer reviewed using the Peer Review of Electronic Search Strategies (PRESS) guideline [24]. The search strategy will employ a combination of the following terms that will be translated as appropriate for each database: "SSRIs," "SNRIs," "Infant, newborn," and "Neonatal Abstinence Syndrome."

Eligibility Criteria and Study Selection

We plan to export all citations to Covidence [Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia. Available at

www.covidence.org] for deduplication and screening by two independent reviewers (AA and SK). Inclusion criteria at the title and abstract stage will include English language studies focused on in utero exposure to SSRIs or SNRIs. Following title and abstract screening, eligible studies will be reviewed by the same reviewers at the full-text level. The inclusion criteria at this stage will include primary studies of any design, either observational or interventional, that provide data regarding FNASS scores of newborns exposed to SSRIs or SNRIs in utero or that provide data regarding pharmacological treatment provided to these newborns. Any disagreements during the study selection process will be resolved through discussion or by consultation with a third reviewer.

Data Collection Process and Data Items

Data extraction will be guided by a modified version of the Cochrane Collaboration's Data collection form: Intervention review – Randomized Controlled Trials (RCTs) and non-RCTs [25]. The collection process will be piloted among all reviewers to determine usability and efficacy of the data extraction form. Following piloting of the form, data will be extracted independently by two reviewers (AA and SK). Any disagreements will be resolved through discussion or by consultation with a third reviewer. We plan to extract information regarding general study characteristics, such as first author, funding source, study year and design. We will also extract information regarding population demographics, such as newborn gestational age and postnatal age, and key data related to the review objectives, including dose and duration of exposure to SSRIs or SNRIs, mean (SD) FNASS scores, and pharmacological treatment for NAS, including first-line medication and adjunctive agents.

Risk of Bias in Individual Studies

The risk of bias of individual studies will be conducted using tools appropriate for the designs of included studies. The risk of bias of randomized controlled trials and cohort studies, and cross-sectional studies will be conducted using the Cochrane Risk of Bias 2.0 tool [26], the Ottawa-Newcastle Risk of Bias Assessment for Observational Studies [27], and the Appraisal tool for Cross-Sectional Studies (AXIS tool) [28], respectively. The risk for bias for case control studies, case reports, and case series will be evaluated using the Joanna Briggs Institute Critical Appraisal Tools Checklists for Case Control Studies, Case Reports and Case Series, respectively [29-31]. The risk of bias assessments will be conducted in duplicate by two reviewers (AA and SK). Any disagreements will be resolved through discussion or by consultation with a third reviewer.

Synthesis

We plan to use RevMan [Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014] to conduct a random effects meta-analysis to yield an overall summary of average FNASS scores in neonates exposed to SSRIs or SNRIs *in utero*. Results will be presented as mean differences and 95% confidence intervals. Statistical heterogeneity of the included studies will be assessed using the I^2 statistic. Low to moderate heterogeneity will be defined as an I^2 of less than or equal to 50% with I^2 greater than 50% considered substantial heterogeneity [32]. As our primary outcome is continuous, publication bias will be assessed using a modified funnel plot and test based on residuals and inverse sample size [33].

Assessment of the Quality (Certainty) of the Evidence

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach [34] will be used to assess the certainty of the evidence for the primary outcome (FNASS score).

Results

The development of preliminary search strategies is currently underway in consultation with a professional librarian. We plan to have finalized all search strategies and to have conducted a comprehensive search of all databases by July 2021.

Discussion

We plan to use the results of our meta-analysis to yield a summary of average FNASS scores in neonates exposed to SSRIs or SNRIs *in utero* (primary outcome). In addition, we aim to compare the resulting FNASS summary score against the proportion of neonates who received pharmacological treatment for NAS (secondary outcome). We will also extrapolate details of the presented pharmacological treatment strategies utilized among neonates with moderate to severe NAS, including first-line medications and adjunctive agents, providing a high-quality data synthesis to inform evidence-based guidelines for the medical management of newborns with NAS following exposure to *in utero* SSRIs and SNRIs.

Conclusions

Increasing trends of depression among young adults of childbearing age [17] combined with concerns for safety regarding the discontinuation of antidepressants during pregnancy [18-20] may contribute to a higher prevalence of newborns with SSRI- and SNRI-induced NAS. While over 90% of newborns with moderate and severe opioid-induced NAS receive pharmacological treatment, symptomatic newborns exposed to maternal antidepressants may not be systematically screened nor treated. This is concerning given the potential for long-term adverse effects related to untreated NAS [16]. Thus, with the proposed systematic review and meta-analysis, we aim to determine the severity of SSRI- and SNRI-induced NAS as well as the proportion of newborns who receive pharmacological treatment for this condition. The strengths of this review

include comprehensive database searches, systematic screening and selection processes, and rigorous risk of bias assessments. As the literature on this topic may employ limited use of study designs that are considered a high level of medical evidence, such as the randomized controlled trial [35], one of our limitations may be the inclusion of studies that are at a low level of medical evidence and their associated limitations. In conducting this review, we hope to provide a high-quality data synthesis to inform the development of standardized, evidence-based guidelines regarding the medical management of newborns with SSRI- and SNRI-induced NAS and ultimately prevent morbidity and mortality among this vulnerable population.

List of Abbreviations Used
AXIS: appraisal tool for cross-sectional studies
CENTRAL: Cochrane central register of controlled trials
FNASS: Finnegan neonatal abstinence scoring system
GRADE: grading of recommendations assessment, development, and evaluation
NAS: neonatal abstinence syndrome
PEO: population, exposure, outcome
PRESS: peer review of electronic search strategies
PRISMA: preferred reporting items for systematic review and meta-analysis
PRISMA-P: preferred reporting items for systematic review and meta-analysis protocols
RCT: randomized controlled trial
SD: standard deviation
SSRIs: selective serotonin reuptake inhibitors
SNRIs: serotonin and norepinephrine reuptake inhibitors

Conflicts of Interest
The author(s) declare that they have no conflict of interests.

Ethics Approval and/or Participant Consent
We will not seek ethics approval or participant consent for the proposed systematic review, as it will involve the collection and analysis of publicly available data.

Authors' Contributions
AA: contributed to the conception or design of the work, drafted the work and revised it critically for important intellectual content, and gave final approval of the version to be published.
SK: contributed to the conception or design of the work, drafted the work and revised it critically for important intellectual content, and gave final approval of the version to be published.

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