Diagnostic Accuracy of the Screening Instruments Used to Identify Postpartum Depression in the Primary Care Setting: Protocol for a Systematic Review and Meta-Analysis

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Protocol

Keywords: Depression, screening instrument, postpartum, primary care setting, systematic review, meta-analysis.

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Abstract

Background

Postpartum depression (PPD) is a prevalent complication of pregnancy, this condition affects maternal and child well-being and functioning. Results from a meta-analysis showed an incidence of 13% PPD cases in the first 12 weeks after labor. Primary care is the first gate and continuing point of care for patients. Despite the controversy of screening and early identification in primary care settings, many PPD cases remain undetected. Given the uncertainty about this issue, screening instruments must be effective in identifying the cases. This systematic review and meta-analyses aim to identify the most suitable postpartum depression screening instrument for use in primary care.

Methods

PubMed, ScienceDirect, and ProQuest databases were used to search using relevant keywords or MeSH, with limitation of publication from January 1st, 2010 through December 31st, 2020. We will include screening studies on postpartum women using validated screening tools followed by validated structured or semi-structured interview for Diagnostic and Statistical Manual of Mental Disorders (DSM) as the reference standard in the primary care setting. Study designs included in the review are cross-sectional and randomized controlled trial without no screening arm on the diagnostic study. We will use a liberal accelerated method on the title and abstract review stage, then perform full-text article reviews on selected studies. Methodological quality will be assessed independently by two authors according to QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2). Extraction of the study data will be undertaken by one reviewer and checked by a second reviewer. Disagreements will be resolved by consensus and including a third investigator as necessary. The test characteristics will be extracted into 2x2 tables for all included studies. Study-specific estimates of sensitivity and specificity with 95% confidence intervals will be displayed in forest plots.

Discussion

The proposed systematic review and meta-analyses will allow us to obtain the most suitable postpartum depression screening instrument for use in primary care.

Systematic review registration:

PROSPERO CRD42020216067

Background
Postpartum depression (PPD) is a prevalent complication of pregnancy, affecting an estimated 10–15% of females after pregnancy (1). Results from a meta-analysis of postpartum depression in 59 research discovered a general incidence of 13% in the first 12 weeks after childbearing (2). Postpartum depression severely affects maternal well-being and functioning (1). The common symptoms include dysphoria, emotional lability, sleep disturbance, confusion, guilt, and suicidal ideation (2). Besides its effect on the mother itself, postpartum depression also has adverse impacts on the child. This effect arises from impaired bonding of maternal-child, maternal withdrawal, disengagement, hostility and short duration of breastfeeding (3). Early therapy of maternal with PPD can decrease these issues (4).

Many cases of PPD remain undetected (4), as many women may be ashamed to tell their feeling (5) or because the health providers do not recognize the symptoms or fail to discuss them (4). Postpartum depression is challenging to identify and manage. Furthermore, healthcare providers may prioritize other health problems directly associated with pregnancy and the fetus or infant (6). Screening and early identification have been proposed but are controversial (7).

Primary care is the first gate and continuing point of care for patients (8). In the context of primary care, in 2009, the United States Preventive Service Task Force (USPSTF), recommended screening when staff-assisted programs are in place to ensure an accurate diagnosis. In contrast, National Institute for Health and Care Excellent (NICE) in 2010 did not recommend routine screening, but primary care physicians should be alert to possible depression in their patients. In 2013, the Canadian Task Force on Preventive Health Care (CTFPHC) recommended screening for depression (6).

In a primary care setting, screening instruments must be effective to identify individuals with or without certain cases (5). Systematic reviews on this issue also differ in their findings (6). Given the uncertainty about this issue, we conduct this systematic review and meta-analysis to identify the most suitable postpartum depression screening instrument for use in primary care.

**Methods**

This protocol was prepared in accordance with the Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines (see Additional file 1) and has been registered in the Prospective Registry of Systematic Review (PROSPERO) database (PROSPERO CRD42020216067). The review results will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

**Eligibility criteria**

Studies will be selected according to the inclusion and exclusion criteria in Tables 1.


Table 1
Criteria for inclusion and exclusion of studies

| Inclusion Criteria                                      | Exclusion Criteria                                                                 |
|---------------------------------------------------------|-------------------------------------------------------------------------------------|
| **Population**                                          | Women in the postpartum period (immediately after labor to 12 months postpartum)   |
|                                                         | Screening before labor                                                              |
|                                                         | Any complication during pregnancy or in their infant, history of major depression,   |
|                                                         | another psychiatric diagnosis                                                       |
| **Intervention**                                        | Isolated screening or screening as a part of a more comprehensive prevention or     |
|                                                         | intervention strategy, using a validated screening instrument for depression.        |
|                                                         | Screening using non-validated instruments                                           |
| **Comparators**                                         | Diagnosed by psychiatry                                                             |
|                                                         | Validated structured or semi-structured interview for DSM                           |
| **Outcomes**                                            | Measure effect such as sensitivity, specificity, accuracy, or AUC (Area Under Curve) |
|                                                         | value                                                                              |
| **Timing**                                              | Published in databases from 2010 till 2020                                          |
| **Setting**                                             | Study located in the primary care setting                                           |
|                                                         | Study located in the intensive care setting                                        |
|                                                         | Healthcare provided by a specialist or tertiary care.                               |
| **Study design**                                        | Randomized controlled trials (RCT) of diagnostic study                              |
|                                                         | Cross-sectional diagnostic study                                                    |
| **Report criteria**                                     | Article in English                                                                  |
|                                                         | Full text provided                                                                 |

According to Cochrane Handbook for Diagnostic Accuracy Test (DTA), in principle, the diagnostic accuracy studies are cross-sectional studies. At the time of inclusion, all patients have clinical uncertainty about their target condition status. The index test and its comparators are intended to reduce uncertainty. The clinical reference standard is the best available method for establishing the presence or absence of the target condition (9). However, an RCT of diagnostic study that compares more than one index test with a screening arm will be included.

Studies for the review in which examining depression screening tools among women who are 4 weeks up to 12 months postpartum in the primary care setting. Studies that included screening process before labor and in complicated pregnancy, also screening process conducted in a non-primary care setting (mental health care, specialist care, tertiary care, intensive care) will be excluded. The depression

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screening tool that will be accounted for review here must be a validated screening instrument with a pre-defined cut-off score to identify patients who may have depression but who have not reported their symptoms to healthcare providers or who have otherwise not been identified as possibly depressed by healthcare providers. The eligible comparator will be diagnostic establishment using validated structured or semi-structured interview for DSM or diagnosed by a psychiatrist.

**Data source and search for studies**

We will search for articles in three databases, PubMed, ScienceDirect, and ProQuest, for English language journal articles published from January 1st, 2010 through December 31st, 2020. Manual searching and “grey” literature will not be included. The complete search strategy showed in Table 2.

| Database     | Term used                                                                 |
|--------------|---------------------------------------------------------------------------|
| PubMed       | (((“screening instruments”) OR “screening tools”) OR “screening scales”) AND depression AND postpartum AND (primary health care OR primary care) |
|              | ((screening [Title]) AND depression [Title]) AND postpartum [Title] (primary health care [Title] OR primary care [Title]) |
| ScienceDirect| ALL (“screening instruments” OR “screening tools” OR “screening scale”) and ALL (depression AND postpartum) and ALL (“primary health care” OR “primary care”) |
| ProQuest     | Depression AND postpartum AND screening AND (“primary health care” OR “primary care”) |

**Study selection**

Search results will be initially uploaded into the citation management database. Duplicate across the search will be identified and removed using this reference manager. The study selection will be done in two stages. In the first stage, the title and abstract review will be done by two reviewers. We will use a liberal accelerated method in which a second reviewer will verify those records deemed not relevant by the first reviewer. Then a full-text article review as the second stage will be completed. Disagreements between reviewers will be resolved by consensus, including a third investigator as necessary. See Fig. 1 for the preliminary PRISMA flow of studies. The screening form draft is available in Additional file 2.

Reports that are co-publications or multiple reports of the same study will be identified at full-text review and labeled as such. Study with a language other than English will be excluded and labeled as “other language”. For full-text screening, articles not available electronically will be ordered via interlibrary loan or by contacting the authors. If the article is not received within 30 days, it will be excluded and the reason for exclusion will be labeled as “full-text not available”. In full-text review, where study eligibility is unclear, authors will be contacted by email twice, 2 weeks apart, for additional information. If no response is received, the article will be excluded and will be included in the list of excluded studies as “unclear”.  

**Data extraction and outcome**
Data extraction for the studies finally selected will be conducted using formatted Excel spreadsheets specifically created for this review. Study characteristics, including country of conduct, author(s), date of publication, number of included participants in each group, and measure of effect will be summarized. Outcomes reported will include sensitivity (Se), specificity (Sp), positive predictive value (PPV), negative predictive value (NPV), and Area Under Curve (AUC) value from each study. Authors of original studies will be contacted if necessary, to clarify inconsistencies in reported results. Full data extraction will be completed by one reviewer and verified by a second reviewer. Inconsistencies were resolved by a third reviewer. Draft for data extraction is available in Additional file 3.

Quality assessment

We will use the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool to assess the risk of bias factors in primary studies (10). QUADAS-2 incorporates assessment of the risk of bias across four core domains: patient selection, the index test, the reference standard, and the flow and timing of assessment. All included studies were assessed for the risk of bias in each domain. The risk of bias was judged as “low”, “high”, or “unclear”. Two reviewers will independently assess the risk of bias with any discrepancies resolved by consensus.

Data synthesis and analysis

Descriptive data will be summarized narratively and presented in two summary tables. The first table will summarize the study design, participants, index test details, the reference standard, and the measure of effect. The second table will summarize details on quality assessment according to QUADAS-2. Data for 2x2 tables of index test against reference standard will be extracted from each study. The true positive, true negative, false positive, and false negative rate will be recorded. If these data are not provided, they will be calculated from raw data wherever possible.

For each study, we will calculate sensitivities, specificities, and their 95% confidence intervals for each reported cut-off. These data will be presented graphically via forest plot with 95% confidence intervals and in a receiver operating characteristic (ROC) space. This will allow for visual inspection of any between-study variability.

For the main analysis, we will use a common threshold (if it exists). A common threshold describes when all of the studies include the same cut-off value or threshold for predicting the target condition. We will only pool studies if they are conducted in similar settings and are deemed applicable and at low risk of bias based on the QUADAS-2 tool. For the meta-analysis, we will fit a summary ROC curve using a bivariate random-effects model. We will derive summary accuracy statistics (sensitivity and specificity) and plot the 95% confidence interval and prediction region in the ROC space. The analysis will be undertaken using an R software package.

An initial assessment of heterogeneity will be performed via visual inspection of forest plots and individual study results in the ROC space. Potential sources of heterogeneity include the following: (1)
publication year, (2) country, (3) index test, (4) cut-off value. Where possible we will explore the impact of covariates by conducting subgroup analysis and by including covariates in the random-effects model.

**Discussion**

Depression is a chronic and disabling condition (12). However, most patients with depression do not receive adequate care (13). Screening for depression is one possible solution to improve depression management (12). There are numerous recommendations to screen for depression in specialty medicine settings (14). In primary care settings, screening instruments must be effective to identify individuals with or without such cases (5).

The proposed systematic review will determine the most suitable screening instrument for postpartum depression cases in the primary care setting. We will address considerations for future research and highlight the implications for primary care practice. The conclusions drawn from this systematic review, once disseminated to policy-makers, health care providers, and researchers, will allow decisions to be made about what screening instrument had to be used for primary care setting.

**Abbreviations**

AUC  
Area Under Curve; CTFPHC: Canadian Task Force on Preventive Health Care’s; DSM: Diagnostic and Statistical Manual of Mental Disorders; DTA: Diagnostic Accuracy Test; NICE: National Institute for Health and Care Excellent; NPV: negative predictive value; PPD: Postpartum Depression; PPV: positive predictive value; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PRISMA-P: Systematic Reviews and Meta-Analyses Protocols; PROSPERO: Prospective Registry of Systematic Review; QUADAS-2: Quality Assessment of Diagnostic Accuracy Studies-2; RCT: Randomized controlled trials; ROC: receiver operating characteristic; Se: sensitivity; Sp: specificity; USPSTF: United States Preventive Service Task Force;

**Declarations**

**Ethics approval and consent to participate**

Not applicable.

**Consent for publication**

Not applicable.

**Availability of data and materials**

Not applicable.
Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

RNA devised the project, the main conceptual ideas and proof outline, SSM and ASDH wrote the manuscript in consultation with RNA, WI helped supervised the project, MH supervised the project. All authors read and approved the final manuscript.

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Figure 1
Draft flow diagram of study selection process (11).

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.

- additionalfile1.docx
- additionalfile2.docx
- Additionalfile3.docx