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Impact of pelvic floor ultrasound in diagnosis of postpartum pelvic floor dysfunction
A protocol of systematic review

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Abstract
Background: This study will appraise the impact of pelvic floor ultrasound (PFU) in diagnosis of postpartum pelvic floor dysfunction (PPPFD).

Methods: Studies that report the impact of PFU in diagnosis of PPPFD will be examined in Cochrane Library, MEDLINE, EMBASE, PSYCINFO, Scopus, Web of Science, Allied and Complementary Medicine Database, CNKI, and WANGFANG up to June 1, 2020. Grey literature sources will also be searched. All potential case-controlled studies (CCSs) exploring the impact of PFU in diagnosis of PPPFD will be considered for inclusion in this study. Data will be extracted from eligible CCSs for data pooling and meta-analysis. Whenever necessary, we will also perform summary effect size, heterogeneity across studies, study quality assessment, and reporting bias.

Results: The present study will estimate pooled outcome effects regarding the impact of PFU in diagnosis of PPPFD.

Conclusion: This study may provide robust evidence to judge the impact of PFU on PPPFD

Systematic review registration: PROSPERO CRD42020187623.

Abbreviations: CCSs = case-controlled studies, CIs = confidence intervals, PFU = pelvic floor ultrasound, POP = pelvic organ prolapse, PPPFD = postpartum pelvic floor dysfunction, SUI = stress urinary incontinence.

Keywords: impact, pelvic floor dysfunction, pelvic floor ultrasound, postpartum

1. Introduction

Pelvic floor dysfunction (PFD) is a common disorder that affects ability to control and coordinate pelvic floor muscles.[1–4] It constitutes a spectrum of pathologies[5] and is associated with stress urinary incontinence (SUI), bowel incontinence, pelvic pain, sexual dysfunction, constipation, and pelvic organ prolapse (POP),[6–9] which significantly affect quality of life for patients with PFD.[10–12] It has been estimated that its prevalence varies from 23.7% to 46.2% of women experience at least 1 PFD,[13,14] and its prevalence in females over 40 years old is between 30% and 50%.[15] Its incidence is reported about 58.70% with about 48.3% for POP and 8.7% for SUI.[16] PFD commonly affects women of all ages, but there is a higher risk for pregnancy women after delivery with PFD, also known as postpartum pelvic floor dysfunction (PPPFD).[17–23] Thus, it is very important to diagnose this condition at early stage.

Pelvic floor ultrasound (PFU) is responsible for diagnosis of PPPFD, and a variety of studies have reported the impact of PFU for diagnosis of PPPFD.[24–27] However, little is known about the impact of PFU in diagnosis of PPPFD at evidence-based medicine level. Thus, in order to better understand this issue, we will conduct a systematic review to address the impact of PFU in diagnosis of PPPFD.

2. Methods

2.1. Study registration

This study has been registered on PROSPERO with CRD42020187623. It has been reported following the guideline of Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol statement.[28]

2.2. Inclusion criteria for study selection
2.2.1. Type of studies. The present study will include case-controlled studies (CCSs) that assessed the impact of PFU in diagnosis of PPPFD.

2.2.2. Type of participants. All adult female patients (over 18 years old) who were diagnosed as PPPFD will be included in this study, regardless educational background, economic status, and severity of PPPFD.

2.2.3. Type of index test. Index test: PFU is used in detecting patients with PPPFD. However, we will exclude combination of PFU and other tests.

Reference test: patients who were detected by magnetic resonance imaging or computed tomography-proven PPPFD will be considered as comparators.

2.2.4. Outcome measurements. Outcomes are sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and diagnostic odds ratio.

2.3. Data sources and search strategy

With the help of an academic librarian, this study will carry out a systematic literature search to find out studies that assess the impact of PFU in diagnosis of PPPFD. We will comprehensively search citations in Cochrane Library, MEDLINE, EMBASE, PSYCINFO, Scopus, Web of Science, Allied and Complementary Medicine Database, CNKI and WANGFANG up to June 1, 2020. In addition, grey literature sources, such as conference abstracts, thesis, and dissertation will be searched. All CCSs focusing on the impact of PFU in diagnosis of PPPFD will be included. We will provide search strategy of MEDLINE in Table 1. We will adapt similar search strategies to other electronic databases.

2.4. Data collection and analysis
2.4.1. Study selection.
Two authors will scan titles and abstracts of studies retrieved utilizing the search strategy from electronic databases and grey literatures. All unconnected studies will be removed. Then, full text of potential studies will be retrieved for inclusion against all inclusion criteria. Any conflicts will be clarified through discussion with a third author. We will summarize study selection in a flow diagram.

2.4.2. Data extraction. Two independent authors will extract data from all eligible studies utilizing data extraction sheet. It includes general information of included studies and patients (such as authors, title, time of publication, country, etc), sample size, inclusion and exclusion criteria, study quality, index and reference tests, and outcomes. Any disagreements will be resolved by a third author through discussion. If any missing or unclear information is identified, we will contact primary authors to request them.

2.5. Quality assessment

All eligible CCSs will be assessed by 2 independent authors using Quality Assessment of Diagnostic Accuracy Studies tool.[29] Any opposition between 2 authors will be cleared up by a third author through discussion.

2.6. Statistical analysis

This study will apply RevMan V.5.3 software (London, UK) and Stata V.12.0 software (StataCorp; USA) to perform data analysis. We will summarize specific characteristics and study findings in

Table 1

Search strategy applied in MEDLINE database.

Number	Search terms
1	pelvic floor dysfunction
2	pelvic- perineal dysfunctions
3	pelvic floor disorder
4	pelvic floor muscles
5	pelvic pain
6	pelvic organ
7	postpartum
8	pregnancy
9	delivery
10	labor
11	Or 1–10
12	pelvic floor
13	ultrasound diagnosis
14	diagnostic imaging
15	ultrasound
16	ultrasonics
17	Or 12–16
18	case-controlled
19	case-control
20	case-referent
21	observational
22	cohort study
23	study
24	studies
25	Or 18–24
26	11 and 17 and 25

tables. We will estimate outcome as descriptive statistics and 95% confidence intervals, and will perform plots of descriptive forest and summary receiver operating characteristic. Heterogeneity will be checked by I^2 statistic. $I^2 \leq 50\%$ suggests low heterogeneity, and Mantel-Haenszel fixed-effects model will be used, while $I^2 > 50\%$ indicates significant heterogeneity, and Mantel-Haenszel random-effects model will be applied. If there is low heterogeneity, we will conduct meta-analysis based on the sufficient eligible studies on the same outcome indicator. If there is substantial heterogeneity, we will carry out subgroup analysis to examine its possible sources.

2.7. Subgroup analysis

This study will perform subgroup analysis according to the different study characteristics, study qualities, and outcomes.

2.8. Sensitivity analysis

This study will conduct sensitivity analysis to examine stability of study findings by removing low quality studies.

2.9. Reporting bias

This study will test reporting bias using funnel plots and associated regression tests.[30,31]

2.10. Ethics and dissemination

This study will only extract data from published studies, thus no ethic approval is required. It will be published in a relevant peer-reviewed journal.

3. Discussion

Although many studies have reported the impact of PFU in diagnosis on PPPFD, no systematic review or/and meta-analysis is conducted to explore the impact of PFU in detection of PPPFD. Thus, this is the first systematic review to comprehensively search and summarize most recent evidence on the impact of PFU in diagnosis of PPPFD, and to synthesize the effect estimates from all included studies. The findings of this study will inform clinical practice and further studies focusing on the impact of PFU in diagnosis of PPPFD.

Author contributions

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