Impact of prenatal ultrasound diagnosis for fetal renal abnormalities

Study Protocol

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Abstract

Background: This study will evaluate diagnostic accuracy and management outcome studies involving patients assessed with prenatal ultrasound diagnosis (PUD) for fetal renal abnormalities (FRA).

Methods: We will search the following electronic databases of MEDLINE, EMBASE, Cochrane Library, Web of Science, Springer, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure for diagnostic accuracy studies from inceptions to the present without language restrictions. Two authors will independently screen studies, collect data, and assess methodological quality. We will use RevMan V.5.3 and Stata V.12.0 software for data pooling and statistical analysis.

Results: In this study, we will assess sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and diagnostic odds ratio to determine the diagnostic accuracy of PUD for the treatment of patients with FRA.

Conclusion: This study will provide latest evidence for the diagnostic accuracy of PUD for FRA.

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Abbreviations: FRA = fetal renal abnormalities, PUD = prenatal ultrasound diagnosis.

Keywords: fetal renal abnormalities, prenatal ultrasound diagnosis, sensitivity, specificity

1. Introduction

Evaluation of fetal anatomy during the trimester period is very important and necessary for fetal.[1–3] It has become a standard practice in most antenatal care set-ups, and has helped to diagnose most structural abnormalities in the fetus.[4–7] It has been estimated that fetal renal anomalies (FRA) accounts for about 20% of all congenital abnormalities in fetal.[8–11] Moreover, this condition can significantly affect prenatal morbidity and mortality.[12–13] Fortunately, prenatal ultrasound diagnosis (PUD) has been reported to identify such condition accurately.[14–20] However, no study has systematically explored this issue. Thus, this study will investigate the diagnostic accuracy of PUD for FRA systematically.

2. Methods

2.1. Objective

This study aims to review clinical outcomes of patients investigated the diagnostic accuracy of PUD for FRA.

2.2. Inclusion criteria for study selection

2.2.1. Type of studies. This study will consider case-controlled studies reporting the diagnostic accuracy of PUD for FRA for inclusion. However, we will exclude all other studies, except case-controlled studies.

2.2.2. Type of participants. In this study, the reports of patients with a suspected FRA investigated using PUD will be included.

2.2.3. Type of index test. Index test: PUD will be applied to diagnose participants with FRA. However, the combinations of PUD with other index tests will be excluded.

2.2.4. Type of outcome measurements. The outcome measurements consist of sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and diagnostic odds ratio.

2.3. Data sources and search strategy

2.3.1. Electronic searches. The following electronic databases will be searched: MEDLINE, EMBASE, Cochrane Library, Web of Science, Springer, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure for diagnostic accuracy studies from...
inceptions to the present without language restrictions. A search strategy for MEDLINE is presented in Table 1. Similar search strategies will also be utilized to other databases.

2.3.2. Other resources. Additional references of included studies and conference proceedings will also be searched.

2.4. Data collection and analysis

2.4.1. Selection of studies. Two authors will independently perform titles and abstracts screening procedures, and all unqualified studies will be excluded. We will read full-text of all remaining studies to check their final eligibility criteria if uncertainty will be obtained. Any conflicts between 2 authors will be solved by consensus with the help of a third author. All study selection will be presented in the flowchart.

2.4.2. Data collection and management. A structured data extraction sheet will be built to facilitate the process of data collection from the studies that have been included. Two authors will independently carry out data extraction. Discrepancies between 2 authors will be solved by consensus with a third author if necessary. We will extract following information of title, first author, year of publication, country, study period, study characteristics, patient characteristics, patient selection, eligibility criteria, index test, reference test, and outcome measurements.

2.5. Methodological quality assessment

This study will assess the study quality for each entered study using Quality Assessment of Diagnostic Accuracy Studies tool by 2 independent authors. A third author will be invited to solve any divergences between 2 authors regarding the assessment of study quality.

| Table 1 |
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| **Search strategy builds in MEDLINE.** |
| Number | Search terms |
| 1 | fetus |
| 2 | fetal |
| 3 | renal |
| 4 | kidney |
| 5 | anatomy |
| 6 | histology |
| 7 | abnormalities |
| 8 | congenital |
| 9 | Or 1–8 prenatal |
| 10 | diagnostic imaging |
| 11 | ultrasound |
| 12 | ultrasonography |
| 13 | ultrasonics |
| 14 | Or 10–14 |
| 15 | case-control studies |
| 16 | control studies |
| 17 | trials |
| 18 | Or 16–21 |
| 19 | studies |
| 20 | Or 15 and 22 |

2.6. Assessment of heterogeneity

We will measure statistical heterogeneity among included studies using $I^2$ statistic. An $I^2$ value $\leq 50\%$ is indicative of a low degree of heterogeneity, while An $I^2$ value $>50\%$ is indicative of a high degree of heterogeneity.

2.7. Statistical analysis

In this study, we will carry out data pooling and statistical analysis using RevMan V.5.3 and Stata V.12.0 software.

2.7.1. Data synthesis. We will pool the data and conduct meta-analysis if heterogeneity is low ($I^2 \leq 50\%$). Otherwise, we will carry out subgroup analysis if the heterogeneity is significant ($I^2 > 50\%$). If there is still very high significant, we will not pool the data, and will perform a bivariate random-effects regression for summary of estimates of sensitivity and specificity.

2.7.2. Subgroup analysis. Subgroup analysis will be conducted on the basis of differences in interventions, comparators, and outcome assessments.

2.7.3. Sensitivity analysis. Sensitivity analysis will be operated by removing low methodological quality studies.

2.7.4. Reporting bias. Reporting bias will be examined using funnel plots if a sufficient number of studies are eligible for inclusion.[22]

2.8. Ethics and dissemination

This study will use secondary data, thus no ethics approval is needed. Its results are expected to be published in a peer-reviewed journal.

3. Discussion

This is the first study to explore the diagnostic accuracy of PUD for FRA in pregnant women. We will comprehensively and systematically search literature sources, as well as the grey record sources to avoid missing more potential studies. The outcomes of sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and diagnostic odds ratio will be utilized to assess the diagnostic accuracy of PUD for FRA. The findings of this study will summarize up-to-date evidence on the diagnosis of PUD for FRA in pregnant women. It will provide helpful evidence for FRA check and future studies.

Author contributions

Conceptualization: Ying Chen, Wei Liu.
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Investigation: Ying Chen, Wei Liu.
Methodology: Ying Chen.
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Validation: Ying Chen, Wei Liu.
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References

[1] Luchi C, Schifano M, Sacchini C, et al. Detailed fetal anatomy assessment in the first trimester at 11, 12 and 13 weeks of gestation. J Matern Fetal Neonatal Med 2012;25:675–8.
[2] Paviova E, Markov D, Ivanov S. Fetal anatomy assessment at 11±0.1±3±6 wg after acquisition of a single 3D volume-myth or reality? Akush Ginekol (Sofia) 2015;54:3–11.
[3] Jabak S, Vigneswaran TV, Charakida M, et al. Initial experience of superb microvascular imaging for key cardiac views in foetal assessment before 15 weeks gestation. Fetal Diagn Ther 2019;9:1–9.
[4] Clayton DB, Brock JWIII. Prenatal ultrasonography: implications for pediatric urology. J Pediatr Urol 2011;7:118–25.
[5] Batukan C, Yuksel A. Prenatal diagnosis and postnatal outcome of pelvic kidneys. Prenat Diagn 2011;31:336–9.
[6] Kanozama K, Yamataka A, Satake S, et al. Associated urologic anomalies in children with solitary kidney. J Pediatr Surg 2004;39:85–7.
[7] Acien P, Acien M. Unilateral renal agenesis and female genital tract pathologies. Acta Obstet Gynecol Scand 2010;89:1424–31.
[8] Levi S, Hyjazi Y, Schaaps JP, et al. Sensitivity and specificity of routine antenatal screening of congenital anomalies by ultrasound: the Belgian multicentric study. Ultrasound Obstet Gynecol 1991;1:102–10.
[9] Grandjean H, Larroque D, Levi S, et al. The performance of routine ultrasonographic screening of pregnancies in the Eurofetus Study. Am J Obstet Gynecol 1991;181:446–54.
[10] Stefos T, Plachouras N, Sotiradis A, et al. Routine obstetrical ultrasound at 18–22 weeks: our experience on 7236 fetuses. J Matern Fetal Med 1999;8:64–9.
[11] Crane JP, LeFevre ML, Winborn RC, et al. A randomized trial of prenatal ultrasonographic screening: impact on the detection, management, and outcome of anomalous fetuses. The RADIUS Study Group. Am J Obstet Gynecol 1994;171:392–9.
[12] Westland R, Schreuder MF, Ket JC, et al. Unilateral renal agenesis: a systematic review on associated anomalies and renal injury. Nephrol Dial Transplant 2013;28:1844–55.
[13] Winding L, Loane M, Wellesley D, et al. Prenatal diagnosis and epidemiology of multicystic kidney dysplasia in Europe. Prenat Diagn 2014;34:1095–8.
[14] Jiang YL, Qi QW, Zhou XY, et al. Prenatal diagnosis of 17q12 microdeletion syndrome in fetal renal abnormalities. Zhonghua Fu Chan Ke Za Zhi 2017;52:662–8.
[15] Clinton CM, Chasen ST. Unilateral fetal renal abnormalities: are they really isolated? J Ultrasound Med 2016;35:561–4.
[16] Dias T, Sairam S, Kumarasiri S. Ultrasound diagnosis of fetal renal abnormalities. Best Pract Res Clin Obstet Gynaecol 2014;28:403–15.
[17] Livera LN, Brookfield DS, Egginton JA, et al. Antenatal ultrasonography to detect fetal renal abnormalities: a prospective screening programme. BMJ 1989;298:1421–3.
[18] Peng XM. Analysis of the effect of prenatal ultrasound examination on the diagnosis of fetal kidney abnormalities in pregnant women. J Contemp Med 2019;17:185–6.
[19] Li SJ. Application value of prenatal ultrasound diagnosis for fetal kidney abnormalities. Imaging Res Med Appl 2018;2:135–6.
[20] Ruan SN, Hu YF. Analysis of prenatal ultrasound diagnosis for fetal kidney abnormalities. Imaging Res Med Appl 2018;2:135–6.
[21] Whiting PF, Rutjes AW, Westwood ME, et al. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Ann Intern Med 2011;155:529–36.
[22] Deeks J, Macaskill P, Irwig L. The performance of tests of publication bias and other sample size effects in systematic reviews of diagnostic test accuracy was assessed. J Clin Epidemiol 2005;58:882–93.