INPLASY PROTOCOL

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Diagnostic accuracy of hysterosalpingosonography for fallopian tubal occlusion of female infertility: A protocol for systematic review and meta-analysis

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Review question / Objective: To evaluate the diagnostic performance of hysterosalpingosonography (Sono-HSG) for fallopian tubal occlusion in the context of female infertility. Eligibility criteria: 2.1.1. Type of study. This study will only include high quality clinical cohort or case control studies that evaluate the diagnostic performance of Sono-HSG in evaluation of fallopian tubal occlusion of female infertility. 2.1.2. Type of patients. The patients should be those who had undergone fallopian tubal occlusion of female infertility. 2.1.3. Intervention and comparison. Fallopian tubal occlusion of female infertility of all patients were assessed with Laparoscopic examination or conventional X-ray hysterosalpingography. 2.1.4. Type of outcomes. The primary outcomes include sensitivity, specificity, positive and negative likelihood ratio, diagnostic odds ratio, and the area under the curve of the summary receiver operating characteristic.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 June 2021 and was last updated on 24 June 2021 (registration number INPLASY202160091).

INTRODUCTION

Review question / Objective: To evaluate the diagnostic performance of hysterosalpingosonography (Sono-HSG) for fallopian tubal occlusion in the context of female infertility.

Condition being studied: Sono-HSG has been increasingly employed. This technique is well tolerated and easily performed and it may not only assess tubal patency but also detect uterine cavity anomalies. In addition, the technique allows simultaneous observation of the ovary and myometrium, avoiding ionizing

radiation. Two-dimensional hysterosalpingo-contrast-sonography (2D-HyCoSy) and three/four-dimensional hysterosalpingo-contrast-sonography(3D/ 4D-HyCoSy) have been applied in fallopian tubal occlusion in women with infertility. High heterogeneity was found for both sensitivity and specificity. No statistically significant differences were found between the methods (p = 0.13). So that they concluded that 2D-HyCoSy has a similar diagnostic performance to 3D/4D-HyCoSy. However, the main limitation of Sono-HSG is that the accuracy of inspection results is largely related to the operator's experience, which means that it has certain subjective factors and is largely dependent on the level of the operators.

METHODS

Participant or population: The patients should be those who had undergone fallopian tubal occlusion of female infertility.

Intervention: Fallopian tubal occlusion of female infertility of all patients were assessed with Laparoscopic examination or conventional X-ray hysterosalpingography.

Comparator: Fallopian tubal occlusion of female infertility of all patients were assessed with Laparoscopic examination or conventional X-ray hysterosalpingography.

Study designs to be included: This study will only include high quality clinical cohort or case control studies that evaluate the diagnostic performance of Sono-HSG in evaluation of fallopian tubal occlusion of female infertility.

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comparison. Fallopian tubal occlusion of female infertility of all patients were assessed with Laparoscopic examination or conventional X-ray hysterosalpingography. 2.1.4. Type of outcomes. The primary outcomes include sensitivity, specificity, positive and negative likelihood ratio, diagnostic odds ratio, and the area under the curve of the summary receiver operating characteristic.

Information sources: PubMed, Web of Science, Cochrane Library, and Chinese biomedical databases will be searched from their inceptions to the May 31, 2021, without language restrictions. The search strategy for PubMed is shown in Table 1. Other online databases will be used in the same strategy.

Main outcome(s): The primary outcomes include sensitivity, specificity, positive and negative likelihood ratio, diagnostic odds ratio, and the area under the curve of the summary receiver operating characteristic.

Quality assessment / Risk of bias analysis:

The quality of selected studies will be independently evaluated according to a tool for the quality assessment of methodological index for non-randomized studies (MINORS). The MINORS criteria included 12 assessment items. Each of these items is scored as "yes" (2), "no" (0), or "unclear" (1). MINORS score ranged from 0 to 24; and score≥17 indicate a good quality. Any disagreements between 2 investigators will be solved through discussion or consultation by a 3rd investigator.

Strategy of data synthesis: The STATA version 15.1 software (Stata Corporation, College Station, TX, USA) will be used for meta-analysis. We calculated the pooled summary odds ratio (OR) and its 95% confidence interval (CI). The Cochran's Q-statistic and I2 test will be used to evaluate potential heterogeneity between studies. If the Q-test shows a P50%, indicating significant heterogeneity, and the random effect model will be employed or if heterogeneity is not significant, the fixed-effects model was used. If it is possible, we

will perform meta-analysis to analyze the pooled outcome data when acceptable homogeneity has been identified. Otherwise, we will conduct subgroup analysis to investigate potential causes for substantial heterogeneity among eligible studies. Sensitivity analysis will be performed to evaluate the influence of a single study on the overall estimate. We will use Begger's funnel plots and Egger's linear regression test to investigate publication bias.

Subgroup analysis: We will conduct subgroup analysis to investigate potential causes for substantial heterogeneity among eligible studies. Sensitivity analysis will be performed to evaluate the influence of a single study on the overall estimate. We will use Begger's funnel plots and Egger's linear regression test to investigate publication bias.

Sensitivity analysis: Sensitivity analysis will be performed to evaluate the influence of a single study on the overall estimate. We will use Begger's funnel plots and Egger's linear regression test to investigate publication bias.

Language: None.

Country(ies) involved: China.

Keywords: hysterosalpingosonography; fallopian tubal occlusion; female infertility.

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