INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Does hysteroscopy improve fertility outcomes in infertile women: a meta-analysis and systematic evaluation

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Review question / Objective: **Can the use of hysteroscopy before IVF/ICSI improve pregnancy outcomes and increase live birth rates in infertile women?**

Information sources: **Computer searches of published relevant literature in PubMed, The Cochrane Library, Embase, China Knowledge Network (CNKI), VIP database (VIP), Wanfang database (Wanfang), and China Biomedical Literature Database (SinoMed) were conducted from the time of database creation to December 10, 2022. In addition, references of the included literature were searched to supplement access to relevant information. The search was conducted with a combination of free words and subject terms.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 February 2023 and was last updated on 22 February 2023 (registration number INPLASY202320099).

INTRODUCTION

Review question / Objective: **Can the use of hysteroscopy before IVF/ICSI improve pregnancy outcomes and increase live birth rates in infertile women?**

Condition being studied: **Diagnostic evaluation for infertility should include assessment of ovulatory function, structure and patency of the female reproductive tract, as well as semen analysis. Ultrasound (US), especially transvaginal ultrasound (TVUS), can be used to screen women for possible ovarian, endometrial, or uterine cavity abnormalities associated**

with fertility problems. This evaluation can be enhanced by hysterosalpingography (HSG), saline infusion/gel drip ultrasound, and diagnostic hysteroscopy [8-9]. With the development of hysteroscopy techniques over the decades, the complications of the operation are becoming less frequent and the safety is greatly improved. As hysteroscopic techniques are closely linked to the development of technology (camera technology, miniature hysteroscopic tips, photo imaging, dilation media, etc.), the technological developments are now sufficient for hysteroscopy. Hysteroscopy is the "gold standard" test for the evaluation of the uterus and ovaries because of its ability to directly visualize the uterine cavity and its associated pathologies and to treat any abnormalities found.

Nevertheless, a practical question remains: whether the gold standard for intrauterine evaluation of hysteroscopy improves reproductive outcomes versus ultrasound or saline infusion ultrasound [10]. With clinical evidence, hysteroscopy may be used as part of the initial infertility workup but is not the preferred test because its effectiveness in improving reproductive outcomes has not been established [11].

METHODS

Participant or population: All infertile women with or without uterine abnormalities diagnosed by ultrasound (US), salpingography (HSG) or SIS/GIS, register during basic infertility screening (including IUI), register before becoming a candidate for any ART, Infertile women who have tried IVF/ICSI for the first time or have experienced one or more failed IVF/ICSI attempts.

Intervention: Trial group intervention: Diagnostic or surgical hysteroscopy was performed during the first infertility test or before the first or subsequent ART attempt (IVF/ICSI).

Comparator: Control group: Hysteroscopy was not performed before first or second attempt of IVF/ICSI.

Study designs to be included: Randomized controlled trails (RCT).

Eligibility criteria: None.

Information sources: Computer searches of published relevant literature in PubMed, The Cochrane Library, Embase, China Knowledge Network (CNKI), VIP database (VIP), Wanfang database (Wanfang), and China Biomedical Literature Database (SinoMed) were conducted from the time of database creation to December 10, 2022. In addition, references of the included literature were searched to supplement access to relevant information. The search was conducted with a combination of free words and subject terms.

Main outcome(s): Primary outcome indicator: live birth rate (LBR), defined as the delivery of a live fetus after 20 weeks of gestation, resulting in at least one live birth. Singleton deliveries, twin deliveries, or multiple pregnancies resulting in one live birth were counted as one live birth.

Additional outcome(s): Secondary outcomes: clinical pregnancy rate, defined as pregnancy diagnosed by ultrasound visualization of one or more gestational sacs, or by clinical signs of pregnancy identified; miscarriage rate, defined as spontaneous miscarriage of a clinical pregnancy before 20 full weeks of gestation; and procedure-related complications, defined as any complication caused by hysteroscopy.

Quality assessment / Risk of bias analysis: The literature was evaluated according to the Risk of Bias Assessment Tool used in the Cochrane systematic reviews. The assessment included random sequence generation, allocation concealment, blinding, completeness of outcome data, selective outcome reporting, and other biases. Results were expressed according to high risk of bias, unclear risk of bias, and low risk of bias.

Strategy of data synthesis: Revman 5.4 statistical software provided by the Cochrane Collaboration was used. Relative

risk (RR) and its 95% confidence interval (CI) were chosen as the statistics for dichotomous variables; weighted mean difference (WMD) or standardized mean difference (SMD) and its 95% confidence interval (CI) were chosen as the statistics for continuous variables. difference (WMD) or standardized mean difference (SMD) and its 95% confidence interval (CI) were chosen as the statistics for continuous variables. Statistical heterogeneity of included studies was analyzed by Q test and combined with the I2 statistic to assess the magnitude of statistical heterogeneity between included studies. When there was no heterogeneity or small heterogeneity between studies (e.g., I2 ≤ 50%), a fixed-effect model was used for Meta-analysis; if there was large heterogeneity between studies (I2 > 50%) and clinical heterogeneity was not significant, a random-effect model was used for Meta-analysis. When significant heterogeneity existed, the source of heterogeneity should be analyzed.

Subgroup analysis: Depending on the need for heterogeneity analysis, two subgroups, first-time IVF and non-first-time IVF, could be established.

Sensitivity analysis: Changes in the combined effect size for each outcome indicator were observed by excluding individual studies one by one.

Country(ies) involved: China.

Keywords: Hysteroscopy; infertility; meta-analysis.

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