INPLASY

Circulating cell-free DNA methylation as early diagnostic biomarkers for ovarian cancer: A comprehensive meta-analysis

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ADMINISTRATIVE INFORMATION

Support - No.

Review Stage at time of this submission - Qilu Hospital of Shandong University.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120075

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 December 2023 and was last updated on 19 December 2023.

INTRODUCTION

Review question / Objective This study aimed to evaluate the value of circulating cfDNA methylation in the early diagnosis of OC.

Rationale In the early stages of OC development, we can use minimal invasive liquid biopsies (serum/plasma, peritoneal fluid, urine, etc.) to obtain circulating cfDNA methylation molecular changes that are more common than genomic alterations such as mutations and copy number variations and are chemically and biologically stable enough.

Condition being studied Recently, next-generation sequencing of circulating cfDNA alterations has yielded impressive initial screening performance, and DNA methylation of specific genes (SEPT9, RASSF1A, APC, GADD45a) has been proposed as a biomarker for diagnosis and prediction of colorectal and breast cancer.

METHODS

Search strategy Heading (MeSH) and keywords: (“ovarian cancer” [MeSH] or “ovarian neoplasms” [MeSH]) and (“DNA methylated” [all fields] or “DNA methylation”[all fields]); Entry Terms (Synonyms) "ovarian cancer" and (" DNA methylated "[all fields] or "DNA methylation").

Participant or population Ovarian cancer.

Intervention No.

Comparator Healthy people.

Study designs to be included Randomized controlled clinical trial (RCT); Prospective clinical trial; Retrospective clinical study.

Eligibility criteria 1) Assess whether it is a circulating cfDNA methylation biomarker. 2) Patients with early and advanced OC, healthy controls, or benign disease of the ovary. 3) Diagnostic analysis of circulating cfDNA/ctDNA methylation in plasma or serum samples, data can be formed into a 2*2 table, there is no limit to the type of test. 4) Original research articles of high quality with no restrictions on publication date. 5) No language restrictions.

Information sources The meta-analysis followed the PRISMA guidelines and the Cochrane Collaboration Group recommendations on the evaluation of diagnostic test accuracy. Search databases Pubmed, Scope, EMBASE, the Cochrane Library and China National Knowledge Infrastructure until 10 November 2023.

Main outcome(s) This study aimed to evaluate the value of circulating cfDNA methylation in the early diagnosis of OC.

Additional outcome(s) Test results must be carefully interpreted in the context of a medic history, physical examination, and imaging evaluation.

Data management Two authors independently searched and extracted the following information from existing studies: author, year of publication, type of study, experimental groups and control groups, sample type, biomarkers, methylation test methods, countries, truncation value, area under curve(AUC) value, positive predictive value(PPV), negative predictive value(NPV), and experimental groups and control groups age.

Quality assessment / Risk of bias analysis We assessed the risk of bias in the selected studies by the Improved Diagnostic Test Accuracy Research Quality Assessment Tool (QUADAS-2).

Strategy of data synthesis We extracted diagnostic data for OC from each study (true positive, false positive, true negative, and false negative), built a stratified 2*2 list, and used the 'midas' command to estimate pooled sensitivity, specificity, pooled positive likelihood ratio(PLR), negative likelihood ratio(NLR), diagnostic odds ratio(DOR), and the corresponding pooled receiver operating characteristics (SROC) curve in the random-effects model.

Subgroup analysis Meta-regression combines the results of multiple studies with variables that vary between studies. Such as study type, sample, test method, number of people studied, etc.

Sensitivity analysis If heterogeneity between studies was recorded, potential sources of heterogeneity were investigated by sensitivity analysis and meta-regression.

Language restriction No language restrictions were imposed.

Country(ies) involved China.

Keywords Circulating cell free DNA, methylation, diagnostic, ovarian cancer, meta-analysis.

Contributions of each author

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