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Meta-analysis of serum amyloid A for the diagnosis of neonatal sepsis: A comprehensive evaluation of diagnostic accuracy and clinical utility

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 July 2024 and was last updated on 13 July 2024.

INTRODUCTION

Review question / Objective To comprehensively evaluate the diagnostic accuracy and clinical utility of serum amyloid A (SAA) as a biomarker for neonatal sepsis through a rigorous meta-analysis approach.

Condition being studied The diagnostic accuracy of serum amyloid A (SAA) in diagnosing neonatal sepsis, considering its role in the acute inflammatory response.

METHODS

Participant or population Neonates suspected of having sepsis, with included studies varying between those involving blood culture-positive sepsis and clinical sepsis cases.

Intervention The primary intervention investigated is the measurement of serum amyloid A levels in neonates to diagnose sepsis.

Comparator Comparison of SAA levels with traditional diagnostic methods like blood cultures, and other biomarkers used in diagnosing neonatal sepsis.

Study designs to be included Prospective cohort studies, retrospective cohort studies, cross-sectional studies, case-control studies.

Eligibility criteria Inclusion criteria include studies evaluating SAA for the diagnosis of neonatal sepsis, with extractable true positive (TP), true negative (TN), false positive (FP), and false negative (FN) values. Exclusion criteria focus on duplicate publications, studies without accessible data, non-Chinese/English literature, studies not involving neonates, and animal studies.

Information sources Systematic searches of databases such as PubMed, Embase, Cochrane Library, CNKI, Wanfang Database, VIP Database, and China Biology Medicine disc (CBM), up to April 13, 2024.

Main outcome(s) The primary outcomes assessed are the true positive, true negative, false positive, and false negative values of SAA in diagnosing neonatal sepsis.

Quality assessment / Risk of bias analysis

Quality assessment of included studies using the QUADAS tool to evaluate the risk of bias and applicability concerns in diagnostic accuracy studies.

Strategy of data synthesis

Data synthesis involved using statistical tools like Stata 17.0 and Meta-Disc 1.4 for calculating pooled sensitivity, specificity, likelihood ratios, and diagnostic odds ratio. Heterogeneity was assessed using Cochran's Q test and the I² statistic. A random-effects model was applied in cases of significant heterogeneity; otherwise, a fixed-effects model was used.

Subgroup analysis

Subgroup analyses were conducted to explore potential variations in sensitivity and specificity among different study settings, such as hospital-based versus community-based settings or according to different diagnostic thresholds of SAA.

Sensitivity analysis

Sensitivity analyses were performed by excluding individual studies to evaluate their impact on the overall meta-analysis results, helping to identify studies that significantly affect the outcomes.

Country(ies) involved China.

Keywords Serum amyloid A protein; Neonatal sepsis; Meta-analysis.

Contributions of each author

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Author 3 - Xiao-Jun Tian.

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