

ABSTRAK

Latar Belakang : Penyakit hepatitis B adalah infeksi serius yang menyerang hati dan disebabkan oleh virus hepatitis B (VHB). Deteksi dini atau skrining infeksi VHB sangat penting untuk mencegah penularan kepada orang lain, memantau respons pengobatan, serta menilai risiko penyakit hati atau kanker hati. Pemeriksaan HBsAg (*hepatitis B surface antigen*) merupakan penanda utama infeksi VHB. Beberapa metode diagnostik seperti *Rapid Diagnostic Test* (RDT), *Electro Chemiluminescence Immunoassay* (ECLIA), dan *Polymerase Chain Reaction* (PCR) tersedia untuk deteksi HBsAg. Metode PCR dianggap sebagai *gold standard* karena sensitivitas dan spesifisitasnya yang tinggi. Namun, RDT dan ECLIA lebih praktis dan sering digunakan di layanan primer. Oleh karena itu, perlu evaluasi performa RDT dan ECLIA dibandingkan dengan PCR untuk menjamin keandalan hasil pemeriksaan.

Tujuan : Menyajikan bukti ilmiah performa uji RDT dan ECLIA *hepatitis B surface antigen* dengan metode PCR sebagai *gold standard* dalam bentuk nilai sensitivitas, spesifisitas, nilai prediksi positif, dan nilai prediksi negatif kedua metode tersebut dibanding PCR.

Metode : Penelitian ini adalah tinjauan sistematis yang menggunakan artikel-artikel observasional (*cross-sectional, cohort, case control*) terkait evaluasi uji RDT dan ECLIA dibandingkan PCR di berbagai negara selama 2015-2025. Pencarian literatur mengikuti panduan PRISMA dan menggunakan basis data seperti Scopus, Pubmed, *Science Direct*, *Web of Science*, dan Google Scholar. Analisis melibatkan ekstraksi data, sintesis informasi, dan penilaian risiko bias menggunakan instrumen QUADAS-2.

Hasil : Berdasarkan 2.970 artikel yang teridentifikasi, 12 artikel memenuhi kriteria inklusi. Hasil pemeriksaan HBsAg menunjukkan nilai sensitivitas, spesifisitas, nilai prediksi positif dan negatif RDT dan ECLIA dibanding PCR bervariasi tergantung jenis RDT, metode PCR, dan karakteristik populasi. Sebanyak 12 jurnal yang ditemukan, didapat nilai sensitivitas >95% sebanyak lima jurnal, spesifisitas >95% sebanyak enam jurnal, NPP >90% sebanyak delapan jurnal, dan NPN >90% sebanyak enam jurnal.

Kesimpulan : Pemeriksaan HBsAg dengan RDT dapat digunakan untuk skrining awal, tetapi metode dengan ECLIA lebih sensitif. Metode PCR tetap menjadi *gold standard* untuk konfirmasi.

Kata Kunci : *Electro Chemiluminescence Immunoassay* (ECLIA), HBsAg, Hepatitis B, *Polymerase Chain Reaction* (PCR), *Rapid Diagnostic Test* (RDT)

ABSTRACT

Background : Hepatitis B is a serious liver infection caused by the hepatitis B virus (HBV). Early detection or screening for HBV infection is crucial to prevent transmission to others, monitor response to treatment, and assess the risk of liver disease or liver cancer. The HBsAg (hepatitis B surface antigen) test is the primary marker of HBV infection. Several diagnostic methods, such as Rapid Diagnostic Tests (RDTs), Electrochemiluminescence Immunoassay (ECLIA), and Polymerase Chain Reaction (PCR), are available for HBsAg detection. PCR is considered the gold standard due to its high sensitivity and specificity. However, RDTs and ECLIAs are more practical and frequently used in primary health care. Therefore, it is necessary to evaluate the performance of RDTs and ECLIAs compared to PCR to ensure the reliability of the test results.

Objective : To present scientific evidence regarding the performance of HBsAg testing using RDTs and ECLIAs compared to PCR as the gold standard, in terms of sensitivity, specificity, positive predictive value, and negative predictive value of both methods compared to PCR.

Methods : This study is a systematic review of observational articles (cross sectional, cohort, and case-control) evaluating RDT and ECLIA tests compared with PCR in various countries during the period 2015 until 2025. The literature search followed PRISMA guidelines and utilized databases such as Scopus, PubMed, Science Direct, Web of Science, and Google Scholar. The analysis involved data extraction, information synthesis, and risk of bias assessment using the QUADAS-2 instrument.

Results : Of the 2,970 articles identified, 12 met the inclusion criteria. The results of HBsAg testing showed that the sensitivity, specificity, positive and negative predictive values of RDT and ECLIA compared with PCR varied depending on the type of RDT, PCR method, and population characteristics. Of the 12 identified journals, five had sensitivity values >95%, six had specificity values >95%, eight had NPP values >90%, and six had NPN values >90%.

Conclusions : HBsAg testing with RDT can be used for initial screening, but ECLIA is more sensitive. PCR remains the gold standard for confirmation.

Keywords : Electro Chemiluminescence Immunoassay (ECLIA), HBsAg, Hepatitis B, Polymerase Chain Reaction (PCR), Rapid Diagnostic Test (RDT)