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Assessing the Diagnostic Accuracy of SD BIOLINE for Detection of Hepatitis C Virus: A Systematic Review and Meta-analysis

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Abstract

Hepatitis C virus (HCV) is a globally widespread ribonucleic acid virus that transmits through blood and sexual contact. Its morbidity and mortality are particularly higher in economically underdeveloped areas. Therefore, an economical and effective diagnostic method for detection of HCV is urgently needed. In this study, we evaluated the diagnostic accuracy of the SD BIOLINE rapid diagnostic test for HCV detection. We searched for studies related to SD BIOLINE and HCV in PubMed, Embase, Web of Science, and the Cochrane Library and then designed inclusion and exclusion criteria. After extracting valid data, the included literature was evaluated with the quality assessment tool Quality Assessment of Diagnostic Accuracy Studies. After our data analysis, the sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, diagnostic accuracy, summary receiver operating characteristic curve, funnel plot, box plot, and Fagan plot of the diagnostic method were determined. Nine articles with nine sets of data were finally included. The sensitivity and specificity were 0.94 and 0.98, respectively, the positive likelihood ratio was 79.53, the negative likelihood ratio was 0.05, the diagnostic odds ratio was 1590.32, and the summary receiver operating characteristic curve was 0.9958. The SD BIOLINE test has the advantages of high sensitivity, high specificity, low cost, and easy operation for diagnosing HCV. Therefore, we recommend using SD BIOLINE for rapid and effective screening of HCV, which is especially applicable for economically underdeveloped areas.

Keywords: SD BIOLINE; HCV; rapid diagnosis

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Author contributions: GXG, WSC, ZJ, ZXY, XQ, MYX, JLQ, LYP and CXJ participated in the design of the project, formulation of the search strategy, and determination of inclusion of exclusion criteria; GXG has made substantial contributions to the conception and design of the work; WSC contributed to the production of figures and table through the analysis tools; WSC, ZXY, JZ and MYX wrote the manuscript; all the researchers read and revised and approved the final version of the manuscript.

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Introduction

Hepatitis C virus (HCV) is an enveloped ribonucleic acid virus, which mainly transmits through blood and sexual contact. Hepatitis C virus infects liver cells and stimulates the body to manufacture nonspecific and specific immune responses, produces corresponding interferons and activates cytotoxic lymphocyte cells and other cells, thereby causing immune damage to the body. Infected liver cell lysis occurs as a result of this immune damage.[1,2] There are 1.75 million new HCV-infected cases each year, most of which are not detected timely or provided with timely treatment. Every year millions of people are at risk of developing liver fibrosis, liver cirrhosis, hepatocellular carcinoma, and other long-term complications that may be fetal.[3,4] World Health Organization (WHO) data show that in terms of epidemiology, HCV patients are currently distributed globally, with more patients in the WHO Eastern Mediterranean Region and the WHO European Region. The prevalence in these two regions in 2015 were 2.3% and 1.5%, respectively. Seventy percent of HCV-infected patients develop chronic hepatitis C, and there is a 10% to 30% chance of developing liver cirrhosis within 20 years. Approximately 400,000 people die each year due to hepatitis C.[3] Therefore, accurate, fast and cheap diagnosis of patients with suspected hepatitis C is very important, especially in countries with underdeveloped economies.[5] Rapid diagnostic tests (RDTs) are single-use methods; nonprofessionals can operate these kits after proper training and give qualitative results intuitively in a short time.[6] SD BIOLINE is an RDT that can be used at the nursing station, with no need for sophisticated and expensive equipment. SD BIOLINE is an anti-HCV immunochromatographic test that detects the recombinant core nonstructural 3 (NS3), NS4 and NS5 antigens,[7] which can quickly and effectively screen out patients with hepatitis C. This diagnostic test is an inexpensive and rapid serological examination.[8] Therefore, it can be widely used in economically underdeveloped

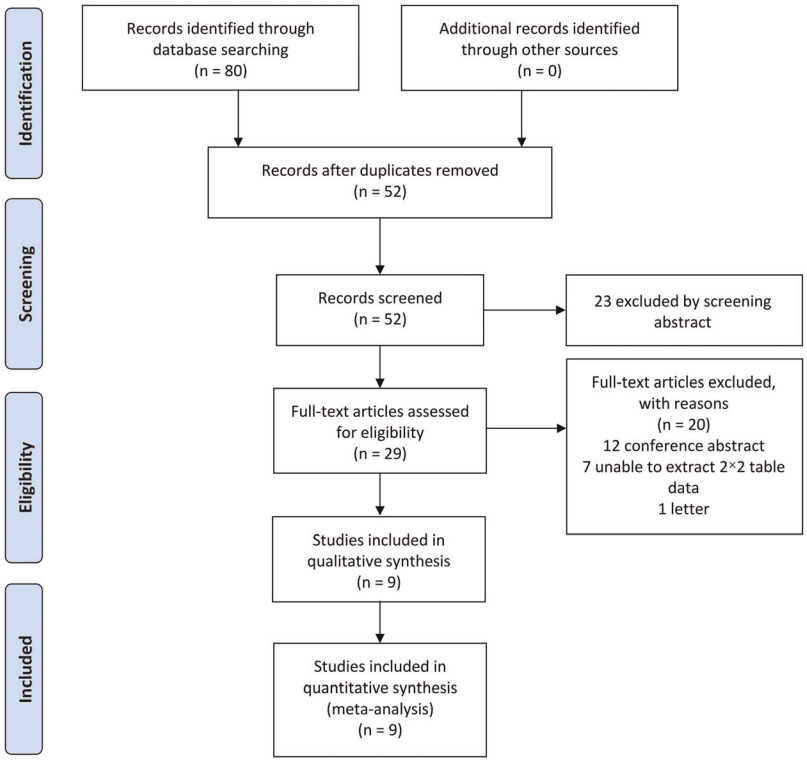

Figure 1. Selection of studies for inclusion in the meta-analysis.

areas.[9] Our meta-analysis aimed to systematically evaluate the diagnostic accuracy of SD BIOLINE for detection of HCV, providing other researchers and healthcare providers with medical evidence for this test, as well as having guiding and clinical significance.

Results

Article selection and inclusion

The exact process of article selection and inclusion is shown in Figure 1. According to the outlined search strategy, a comprehensive and detailed search was conducted in the major databases. We collected a total of 80 articles, including 18 from PubMed, 40 from Embase, 0 from the Cochrane Library, and 22 from Web of Science, 28 of which were duplicates. After a general reading of the titles and abstracts, 23 articles were excluded. The remaining 29 articles were chosen for a full-text reading. Among them, seven articles were removed for the inability to extract the 2 × 2 data form; 12 conference abstracts and one letter were furthermore eliminated. Eventually, we included nine articles altogether and nine groups of data were extracted for meta-analysis (Figure 1).[3,5,7,10–15]

Table 1

Characteristics of the included studies

Author	Country	Year of publication	No. Patients	Source of specimens	Study design	Specimens type	Sensitivity	Specificity	True positive frequency
Singh[10]	India	2022	3254	Clinical samples	Prospective	Plasma samples	0.9755	0.9671	358
Jargalsaikhan[5]	Mongolia	2020	270	Clinical samples	Prospective	Serum samples	0.967	0.989	87
Waheed[11]	Pakistan	2019	300	Clinical samples	Prospective	Blood samples	0.9759	1	203
Sun[12]	Cambodia	2019	421	Clinical samples	Prospective	Blood samples	0.9926	0.9934	268
Mane[3]	India, US	2019	460	Clinical samples	Prospective	A mix of both serum and plasma samples	0.994	1	159
Mahajan[13]	India	2019	86	Clinical samples	Retrospective	Blood samples	0.72	1	49
Kweon[14]	Korea	2019	1581	Clinical samples	Prospective	Serum samples	0.9157	0.9903	413
Waheed[15]	Pakistan	2017	100	Clinical samples	Prospective	Blood samples	0.8333	1	60
Kim[7]	Korea	2013	100	Clinical samples	Retrospective	Serum samples	0.788	1	52

ECLIA, electrochemiluminescence immunoassay; ELISA, enzyme-linked immunosorbent assay; F, female; HCV, hepatitis C virus; M, male; PCR, polymerase chain reaction; RNA, ribonucleic acid.

Research characteristics and quality assessment

We extracted the author's name, research location, publication year, research design, detection system, strain source and other information from the nine included studies (Table 1). In addition, we conducted the revised Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) quality assessment of the included studies (Figure 2), which was customized for assessing the risk of bias of diagnostic accuracy studies. In conclusion, our results suggested that our systematic review and meta-analysis presented relatively high-quality data and analyses.

Accuracy of SD BIOLINE for HCV detection

The diagnostic accuracy of the SD BIOLINE test was identified using a random-effects model. The pooled sensitivity was 0.94 [95% confidence interval (CI) = 0.93–0.95, I^2 = 93.1%] (Figure 3A), the pooled specificity was 0.98 (95% CI = 0.97–0.98, I^2 = 83.4%) (Figure 3B), the positive likelihood ratio was 79.53 (95% CI = 28.49–221.99, I^2 = 84.7%) (Figure 3C), the negative likelihood ratio was 0.05 (95% CI = 0.02–0.13, I^2 = 95.2%) (Figure 3D), the diagnostic odds ratio was 1590.32 (95% CI = 659.94–3832.38, I^2 = 56.9%) (Figure 3E) and the area under the curve shown in the summary receiver operating characteristic analysis was 0.9958 (Figure 3F). These results indicate that SD BIOLINE had an outstanding performance for detection of HCV; for example, the sensitivity and specificity were high and close to the level of the gold standard.

Assessment of publication bias

We used Stata 12.0 software to make funnel charts, bivariate box charts and Fagan charts. First of all, we found from the funnel chart (Figure 4A) that the distribution of dots on both sides was asymmetric, and since the *P* value was 0.882, which was higher than 0.05, the possibility of publication bias was low. Moreover, it was found from the bivariate box diagram (Figure 4B) that there was heterogeneity in the literature contained in this study. The Fagan chart showed that for a sample with a predicted probability of 50%, the posttest probability of a positive result was 99%, and the posttest probability of a negative result was 5% (Figure 4C).

Discussion

The main cause of chronic hepatitis and liver disease globally is HCV, which has become a global health problem that needs to be resolved. Only one fifth of HCV-positive individuals are aware of their disease status. Based on incomplete statistics, in low-income and middle-income countries, the awareness of positive individuals is as low as 8%, while these countries bear more than 60% of the diseases burden.[11,12] RDT kits can not only reduce the need for well-trained health workers but also replace standard detection methods, such as enzyme-linked immunosorbent assay (ELISA), for a preliminary screening, thereby helping detect hepatitis C more quickly. Therefore, using a high-quality, low-cost and high-sensitivity RDT kit is vital for HCV screening. SD BIOLINE is not only simple and cheap, but it also can quickly and effectively screen out patients with hepatitis C.[12]

The pooled sensitivity of the SD BIOLINE test to detect HCV was 0.94 and its pooled specificity was 0.98 (Figure 2B). For comparison, the diagnostic accuracy of the gold standard ELISA method for HCV detection provided a similar sensitivity (93.2%) and specificity (99.2%) in a meta-analysis of 1177 samples from five studies.[16] In addition, in another meta-analysis of 1423 samples from six studies, its sensitivity was 90.8%.[16] Based on these meta-analyses, the SD BIOLINE test and the gold standard ELISA method therefore display a similar sensitivity and specificity.

Equipment for fully automated quantitative RT-PCR ranges from US $45,000 to $75,000, which is quite expensive and therefore cannot be popularized as an ordinary test. The ELISA detection method requires medical personnel and other related professionals to operate, and it can only be operated in a specialized medical field, which is characterized by relatively complicated operations. As an RDT method, SD BIOLINE has been mass produced in many countries, such as India, South Korea, and the United States, and it can be readily purchased. The operation method for this kind of test is simple and it does not require professional medical personnel to carry out. Furthermore, it can be carried out everywhere because it is portable. Another advantage is that it makes the diagnosis very rapid, because it can show visually verifiable results within 20 minutes.[5] The advantages of low price, simple operation and rapidity cannot be achieved by the ELISA tests. Combining with economic factors and its widespread use, these advantages fit the needs of low-income countries.

Table 1

Characteristics of the included studies, Continued

False positive frequency	False negative frequency	True negative frequency	Gold standard	Experimental diagnosis	Age of patients	Gender	Ethnicities	Assay method
95	9	2792	Real time PCR	SD BIOLINE	41.72 (0–80)	Males: 3034 (93.24%); Females: 220 (6.76%)	Mixed-race	SD BIOLINE HCV test
2	3	178	(ELISA) HCV-Ab 3rd generation ELISA	SD BIOLINE	52.2 (21–75)	Males:41 (46%)	Mongoloid	SD BIOLINE HCV test
0	5	92	ECLIA Roche anti-HCV II	SD BIOLINE	Not reported	Not reported	Mixed-race	SD BIOLINE HCV test
1	2	150	ECLIA Roche anti-HCV II	SD BIOLINE	54 (45–61)	Females: 268 (63.7%)	Malay	SD BIOLINE HCV test
0	1	300	ELISA	SD BIOLINE	Not reported	Not reported	Mixed-race	SD BIOLINE HCV test
0	19	18	HCV RNA	SD BIOLINE	47.5 (12–79)	Males: 54 (62.8%)	Mixed-race	AlereTrueline (SDBIOLINE; Haryana, India)
11	38	1119	Architect anti-HCV assay	SD BIOLINE	Not reported	Not reported	Mongoloid	SD BIOLINE HCV test
0	12	28	ECLIA	SD BIOLINE	18–55	Not reported	Mixed-race	SD BIOLINE anti-HCV
0	14	34	Recombinant immunoblot assay	SD BIOLINE	57 (9–87)	Males: 56 (56%); Females: 44 (44%)	Mongoloid	SD BIOLINE HCV test

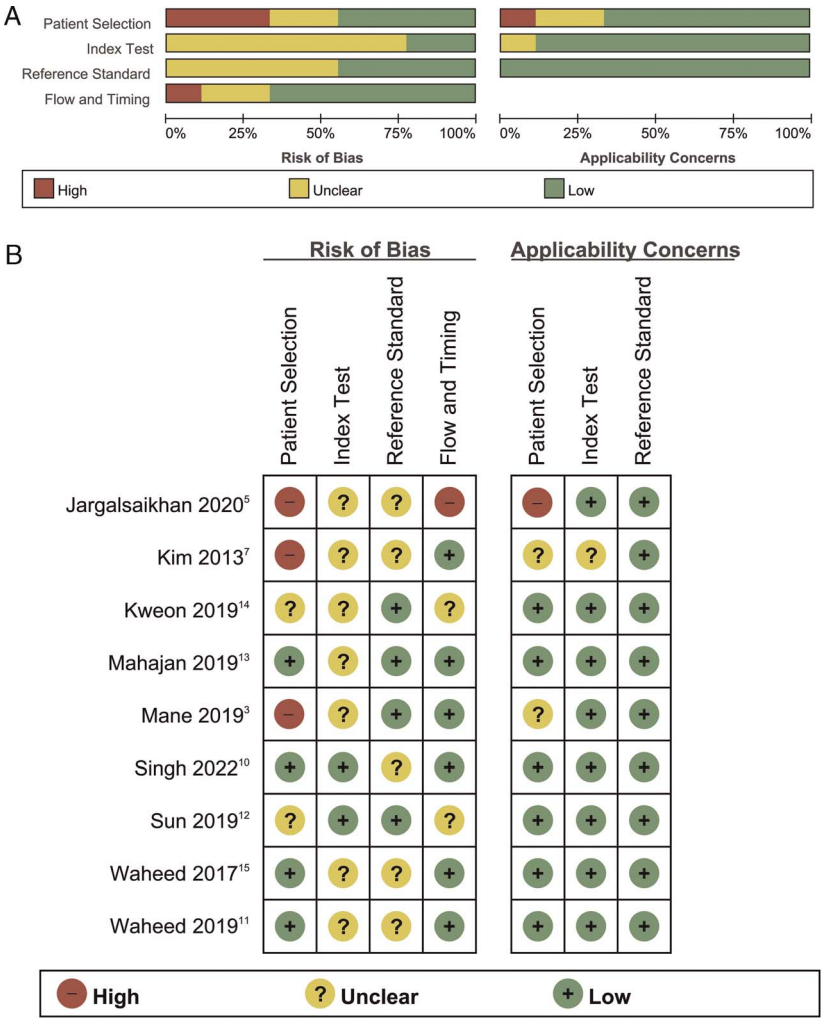

Figure 2. Quality assessment of the SD BIOLINE test for detection of HCV. A: Overall quality assessment of the included studies about SD BIOLINE-based detection of HCV. B: Quality assessment of the individual studies about SD BIOLINE-based detection of HCV. HCV, hepatitis C virus.

Of course, RDTs also have corresponding limitations. Compared with the pooled specificity of 0.98, the pooled sensitivity of the SD BIOLONE test was 0.94. The detection rate is therefore relatively low. Furthermore, our analysis included a total of nine studies with nine sets of data and a total of 6572 samples, which is therefore limited in sample numbers. Moreover, eight of the nine data sets are from Asia, and one is from India and the United States. Therefore, conclusions might not be universal and more applicable to Asian countries. In addition, we did not perform subgroup analysis on factors, such as age and gender, to exclude the influence of factor biases. The most important way to overcome these limitations is to enlarge the sample numbers and conduct research in different regions and more fields to reduce these potential biases.

Finally, our analyses show that the SD BIOLINE test detects HCV with high sensitivity and specificity. It is also very convenient and fast. The detection of HCV by SD BIOLINE tests has great potential in clinical settings. If follow-up studies can improve the limited sample numbers investigated in this study and further studies prove the feasibility of this test, it can better help relevant areas to perform efficient HCV diagnosis and screening.

Materials and methods

Research design

Our research data were collected before January 2023 from the PubMed, Embase, Web of Science and Cochrane Library databases. We performed a systematic review on HCV detection by SD BIOLINE, explored its diagnostic accuracy and conducted a meta-analysis.

Search strategy

SCW, JZ, YXM and XYZ searched for "HCV [all synonyms] and SD BIOLINE [all synonyms]" in PubMed, Embase, Web of Science and Cochrane Library and collected related articles before January 2023. According to standard guidelines and pre-established inclusion and exclusion criteria,[17] all retrieved documents were

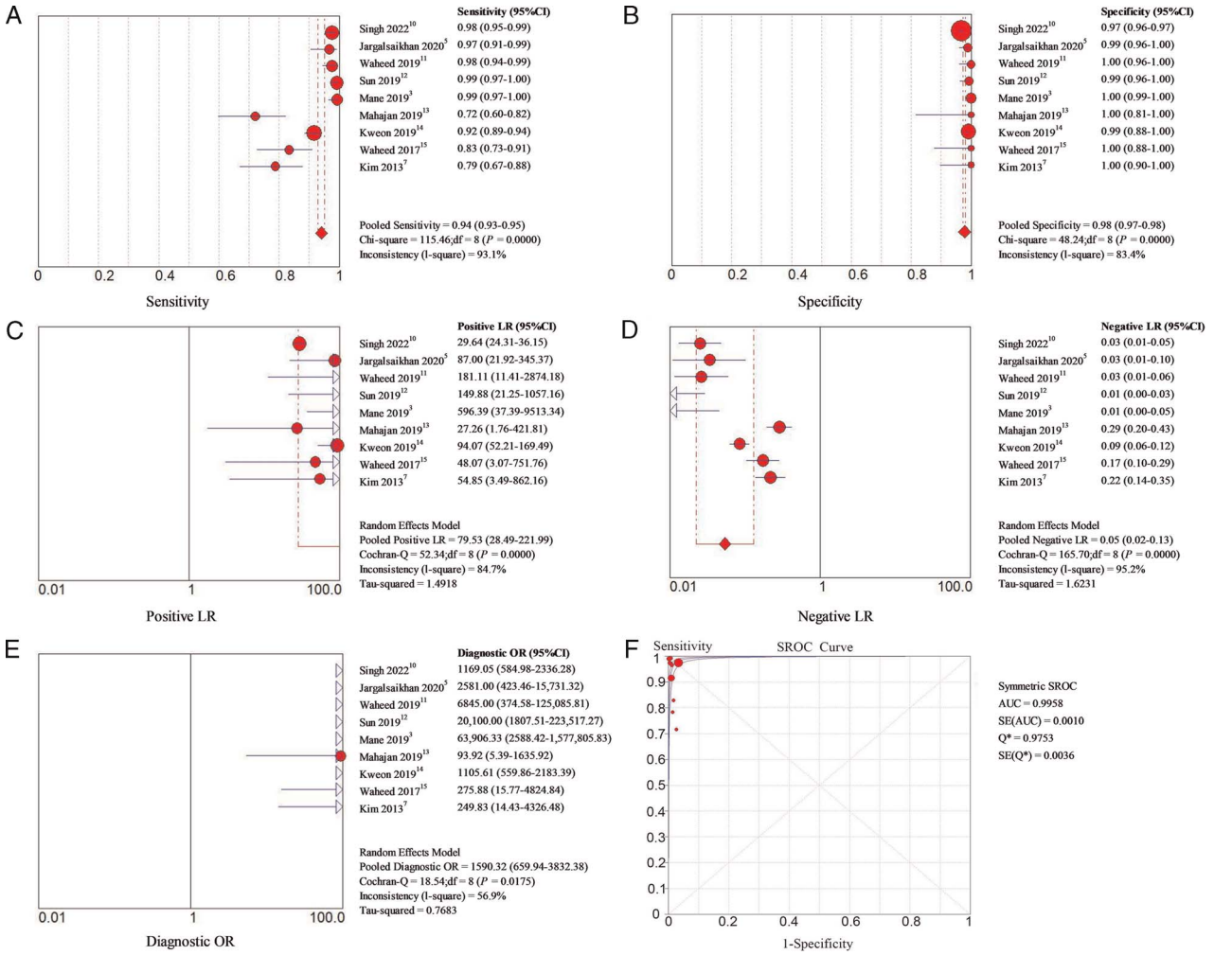

Figure 3. Accuracy of the SD BIOLINE test for detection of HCV. Using meta-disc software, the sensitivity, specificity, positive LR, negative LR, diagnostic OR and SROC curve were obtained according to nine groups of 2 × 2 table data. A: Sensitivity of the SD BIOLINE test for detection of HCV. B: Specificity of the SD BIOLINE test for detection of HCV. C: Forest plots of the combined positive LR of the SD BIOLINE test for the diagnosis of HCV infection. D: Forest plots of the combined negative LR of the SD BIOLINE test for the diagnosis of HCV infection. E: Forest plots of the combined diagnostic OR of the SD BIOLINE test for the diagnosis of HCV infection. F: SROC curve of the SD BIOLINE test for HCV detection. CI, confidence interval; HCV, hepatitis C virus; LR, likelihood ratio; OR, odds ratio; SROC, summary receiver operating characteristic.

screened and systematically reviewed, and the required data were extracted from the articles. Divergence, if there were any, would be resolved through mutual discussion within the group.

Inclusion and exclusion criteria

Before screening and retrieving articles, we established inclusion and exclusion criteria based on Participants, Intervention, Control, Outcome, Study design (PICOS) criteria.

The inclusion criteria were as follows: (i) the purpose was to evaluate the accuracy of SD BIOLINE for detection of HCV; (ii) whether the literature research method was a diagnostic test for HCV; (iii) the research provided authentic and reliable data, such as true positive, false positive, true negative, false negative, sensitivity and specificity; and (iv) English literature only.

The exclusion criteria were as follows: (i) the study did not clarify the gold standard used; (ii) the data provided by the research was not sufficient to calculate the sensitivity and specificity; and (iii) the types of documents were repeated publications, abstracts, conference abstracts, case reports, comments and posters.

Data extraction

We extracted data from the documents that met the inclusion criteria. We first extracted the data of the four-grid table into one table, then created an Excel table and named it a feature table. The table was used to include the first author of the literature, country, published year, number of patients, source of specimens, study design, patients type, sensitivity, specificity, true positive frequency, false positive frequency, false negative frequency, true negative frequency, gold standard, experimental diagnosis, age of patients, gender, ethnicities and assay method. To prevent omissions, two researchers conducted the data extraction separately; when there was a difference, a third researcher conducted the verification.

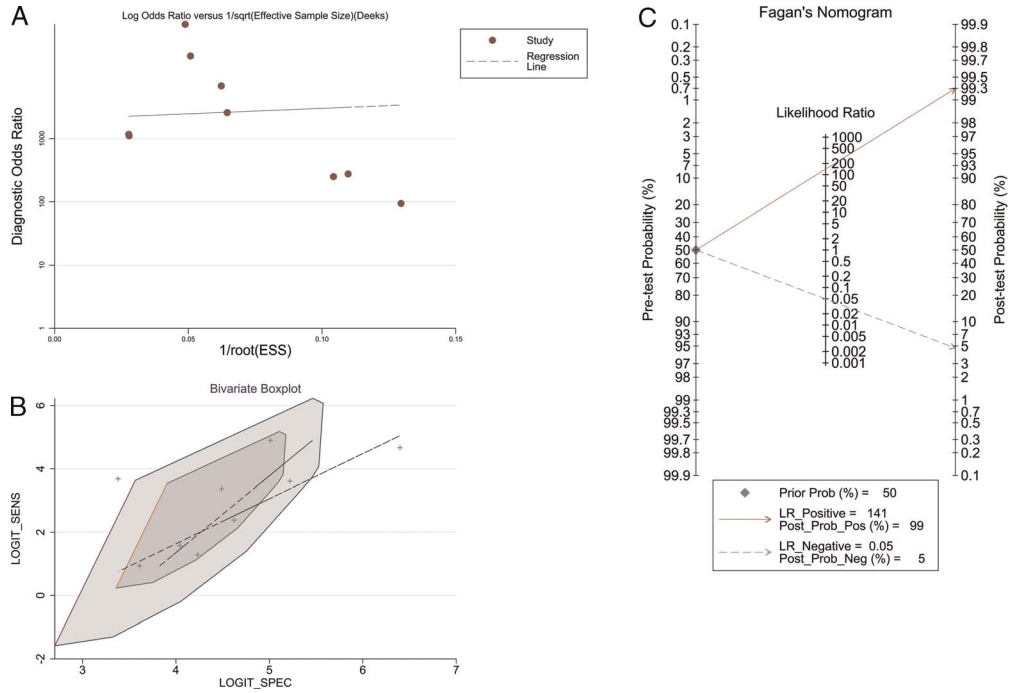

Figure 4. Assessment of publication bias for included studies reporting on the SD BIOLINE test for detection of HCV. Using Stata 12.0 software, the funnel chart, bivariate box chart and Fagan chart were produced based on 9 groups of 2 × 2 table data. A: Deeks' funnel plot asymmetry test to assess publication bias for studies reporting the SD BIOLINE test for detection of HCV. B: Bivariate boxplot of the relationship between sensitivity and specificity. C: Fagan nomogram of disease probabilities based on Bayes' theorem. ESS, effective sample size; LOGIT-SENS, LOGIT-sensitivity; LOGIT-SPEC, LOGIT-specificity; LR, likelihood ratio; Prob, probability; Pos, positive; Neg, negative.

Quality assessment

The included articles were evaluated by the QUADAS-2 tool in Review Manager 5.3 software. Eleven questions were evaluated from four evaluative points: patient selection, index test, reference standard, patient flow and time. "YES" was filled in when it met, "No" if it did not correspond, and "Obvious" if the relevant question was not indicated. This step was completed by four researchers, preventing possible mistakes made by subjective guesswork. Stata12.0 software was used to layout a Deek's funnel chart, a binary box chart and a Fagan chart.

Statistical analysis

We used Meta-DiSc software to calculate the sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, diagnostic odds ratio, summary receiver operating characteristic curve and area under the curve. In terms of the evaluation of heterogeneity, we used I^2 and Q indexes to analyze the heterogeneity of various literature studies. When there was heterogeneity, we used the random-effects model, and when there was no heterogeneity, we used the fixed effects model.

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References

[1] Chigbu DI, Loonawat R, Sehgal M, Patel D, Jain P. Hepatitis C virus infection: host-virus interaction and mechanisms of viral persistence. *Cell* 2019;8(4):376. https://doi.org/10.3390/cells8040376

[2] Zeisel MB, Felmlee DJ, Baumert TF. Hepatitis C virus entry. *Curr Top Microbiol Immunol* 2013;369:87–112. https://doi.org/10.1007/978-3-642-27340-7_4

[3] Mane A, Sacks J, Sharma S, et al. Evaluation of five rapid diagnostic tests for detection of antibodies to hepatitis C virus (HCV): a step towards scale-up of HCV screening efforts in India. *PloS One* 2019;14(1):e0210556. https://doi.org/10.1371/journal.pone.0210556

[4] Ringelhan M, McKeating JA, Protzer U. Viral hepatitis and liver cancer. *Philos Trans R Soc Lond B Biol Sci* 2017;372(1732):20160274. https://doi.org/10.1098/rstb.2016.0274

[5] Jargalsaikhan G, Eichner M, Boldbaatar D, et al. Sensitivity and specificity of commercially available rapid diagnostic tests for viral hepatitis B and C screening in serum samples. *PloS One* 2020;15(7):e0235036. https://doi.org/10.1371/journal.pone.0235036

[6] World Health Organization. *WHO Guidelines on Hepatitis B and C Testing*. Available at: https://www.ncbi.nlm.nih.gov/books/NBK442272/. Accessed December 14, 2020.

[7] Kim MH, Kang SY, Lee WI. Evaluation of a new rapid test kit to detect hepatitis C virus infection. *J Virol Methods* 2013;193(2):379–382. https://doi.org/10.1016/j.jviromet.2013.07.005

[8] Negash M, Kassu A, Amare B, Yismaw G, Moges B. Evaluation of SD BIOLINE *H. pylori* Ag rapid test against double ELISA with SD H. pylori Ag ELISA and EZ-STEP *H. pylori* Ag ELISA tests. *BMC Clin Pathol* 2018;18:4. https://doi.org/10.1186/s12907-018-0071-6

[9] Van Den Heuvel A, Smet H, Prat I, et al. Laboratory evaluation of four HIV/syphilis rapid diagnostic tests. *BMC Infect Dis* 2019;19(1):1. https://doi.org/10.1186/s12879-018-3567-x

[10] Singh RM, Huidrom S, Dutta S, Sadhukhan PC, Singh KL. Comparative evaluation of three diagnostic tools for the detection of hepatitis C virus among high-risk individuals in a tertiary care centre of Northeast India. *J Clin Diagn Res* 2022;16(7):DC13–DC17. https://doi.org/10.7860/jcdr/2022/56521.16610

[11] Waheed Y, Najmi MH, Aziz H, et al. Evaluation of three rapid screening tests for detection of hepatitis C antibodies on mass scale. *Crit Rev Eukaryot Gene Expr* 2019;29(1):25–28. https://doi.org/10.1615/CritRevEukaryotGeneExpr.2018025062

[12] Sun C, Iwamoto M, Calzia A, et al. Demonstration of the diagnostic agreement of capillary and venous blood samples, using hepatitis-C virus SD Bioline(©) rapid test: a clinic-based study. *J Clin Virol* 2019;111:39–41. https://doi.org/10.1016/j.jcv.2018.12.008

[13] Mahajan S, Agarwal R, Rawat V, Kumar G, Sharma MK, Gupta E. Comparative evaluation of three rapid immunochromatographic test assays with chemiluminescent microparticle immunoassay for the detection of hepatitis C virus antibody. *Virus* 2019;30(3):373–379. https://doi.org/10.1007/s13337-019-00542-5

[14] Kweon OJ, Lim YK, Kim HR, Kim TH, Lee MK. Analytical performance of newly developed rapid point-of-care test for the simultaneous detection of hepatitis A, B, and C viruses in serum samples. *J Med Virol* 2019;91(6):1056–1062. https://doi.org/10.1002/jmv.25405

[15] Waheed Y, Najmi MH, Aziz H, Waheed H, Imran M, Safi SZ. Prevalence of hepatitis C in people who inject drugs in the cities of Rawalpindi and Islamabad, Pakistan. *Biomed Rep* 2017;7(3):263–266. https://doi.org/10.3892/br.2017.959

[16] Freiman JM, Tran TM, Schumacher SG, et al. Hepatitis C core antigen testing for diagnosis of hepatitis C virus infection: a systematic review and meta-analysis. *Ann Intern Med* 2016;165(5):345–355. https://doi.org/10.7326/m16-0065

[17] Chen CM, Ouyang S, Lin LY, et al. Diagnostic accuracy of LAMP assay for HBV infection. *J Clin Lab Anal* 2020;34(7):e23281. https://doi.org/10.1002/jcla.23281

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