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Diagnostic accuracy of commercial rapid point-of-care tests for hepatitis B e antigen (HBeAg) in Senegal, West Africa

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BACKGROUND

- To achieve the WHO's global HBV elimination goal, it is important to scale up screening, clinical staging and antiviral treatment in low- and middle-income countries (LMICs) with high HBV prevalence
- Measurement of HBV DNA, an essential marker for treatment eligibility, is not accessible and affordable in LMICs
- Hepatitis B e antigen may be useful alternative in indicating levels of viral replication
- For example, the risk of mother-to-child transmission (MTCT) with timely birth dose vaccine is:[1,2]
  - 0% in infants born to HBeAg-negative mothers
  - 20-30% in those born to HBeAg-positive mothers
- There are few commercially available rapid diagnostic tests for HBeAg, which may be adapted to resource-poor settings. However, their performances have been poorly evaluated.

OBJECTIVES

- To assess the sensitivity and specificity of commercially available rapid immunochromatographic assays for HBeAg detection using a reference test: chemiluminescent microparticle immunoassay (CMIA, Architect, Abbott)

CONCLUSIONS

- HBeAg is a good marker to indicate high viral load (sen 89% spe 97%) using reference serology test (Architect), but not so using point-of-care tests
- Point-of-care tests for HBeAg had high diagnostic specificity, but remarkably low diagnostic sensitivity
- This may be related with their low analytical sensitivity: limit of detection is
  - 0.5 PEIU/ml for Architect
  - >100 PEIU/ml for the point-of-care tests (see figure)
- Urgent need to develop/evaluate alternative assay for HBV DNA, adapted to LMICs

METHODS

- Case-control study using stored sera from HBsAg-positive patients referred to the Institut Pasteur de Dakar, Senegal, between 2014 and 2017 for HBV DNA measurement
- Cases: 114 serum samples positive for HBsAg & HBeAg by Architect, Abbott
- Controls: 196 serum samples positive for HBsAg but negative for HBeAg by Architect, Abbott
- Reference test
  - HBeAg quantified using commercial kit (Abbott)
- Index tests
  - SD Bioline (Standard Diagnostics, South Korea)
  - Insight (Tulip Diagnostics, India)

- Two examiners were blinded to the case/control status

RESULTS 1

- Characteristics of cases and controls

	HBeAg(+) cases (n=114)	HBeAg(-) controls (n=196)	p-value
Male sex	70.2%	65.8%	0.4
Median age (years, IQR)	31 (22-38)	37 (31-47)	<0.001
Median HBV DNA levels (log10 IU/ml, IQR)	7.9 (7.1-8.6)	3.1 (2.4-3.9)	<0.001
Median HBeAg levels (log10 PEIU/ml, IQR)	1.6 (0.8-2.7)	N/A	N/A

REFERENCES

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[2] Machaira M, Papaevangelou V, Vouloumanou EK, et al. Hepatitis B vaccine alone or with hepatitis B immunoglobulin in neonates of HBsAg+/HBeAg- mothers: a systematic review and meta-analysis. J Antimicrob Chemother, 2015.

CONFLICTS OF INTEREST

We declare that we do not have any conflict of interest.

RESULTS 2

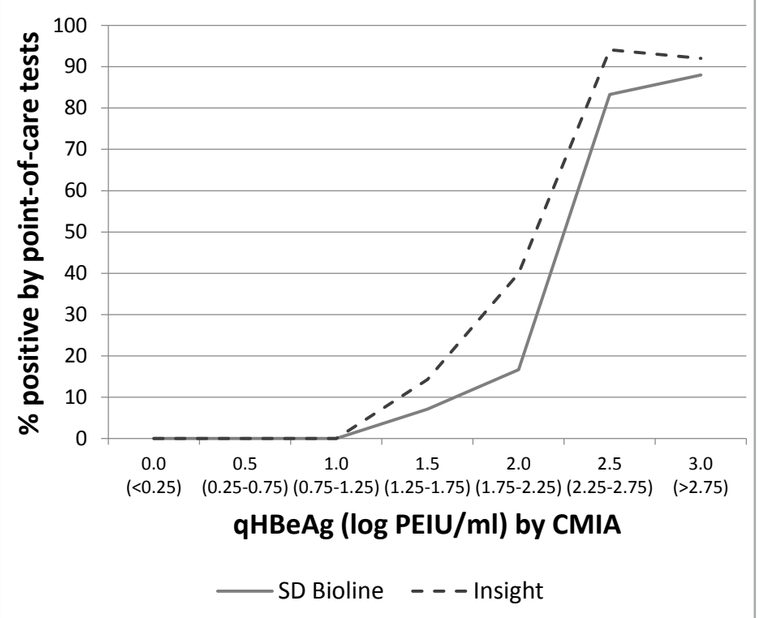
- Inter-rater reliability between two examiners (PABAK: prevalence-adjusted bias-adjusted kappa)

	Kappa (95% CI)	PABAK (95% CI)
SD Bioline	0.93 (0.87-0.99)	0.97 (0.93-1.00)
Insight	0.83 (0.75-0.92)	0.91 (0.85-0.97)

- Diagnostic accuracy to detect HBeAg

	Sensitivity (95% CI)	Specificity (95% CI)
SD Bioline	35.8 (26.8-45.5)	100 (98.1-100)
Insight	42.0 (32.2-52.3)	100 (98.1-100)

- % positive result at different levels of qHBeAg



- Diagnostic accuracy of HBeAg tests to detect high HBV DNA levels (200,000 IU/ml)

	Sensitivity (95% CI)	Specificity (95% CI)
Architect	88.6 (81.6-93.6)	97.3 (93.9-99.1)
SD Bioline	33.1 (24.7-42.3)	100 (98.0-100)
Insight	38.5 (29.4-48.3)	100 (98.0-100)

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