

Characterization of a novel *Helicobacter pylori* East Asian-type CagA ELISA for detecting patients infected with various cagA genotypes

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Abstract:

Currently, Western-type CagA is used in most commercial *Helicobacter pylori* CagA ELISA kits for CagA detection rather than East Asian-type CagA. We evaluated the ability of the East Asian-type CagA ELISA developed by our group to detect anti-CagA antibody in patients infected with different cagA genotypes of *H. pylori* from four different countries in South Asia and Southeast Asia. The recombinant CagA protein was expressed and later purified using GST-tag affinity chromatography. The East Asian-type CagA-immobilized ELISA was used to measure the levels of anti-CagA antibody in 750 serum samples from Bhutan, Indonesia, Myanmar, and Bangladesh. The cutoff value of the serum antibody in each country was determined via Receiver-Operating Characteristic (ROC) analysis. The cutoff values were different among the four countries studied (Bhutan, 18.16 U/mL; Indonesia, 6.01 U/mL; Myanmar, 10.57 U/mL; and Bangladesh, 6.19 U/mL). Our ELISA had better sensitivity, specificity, and accuracy of anti-CagA antibody detection in subjects predominantly infected with East Asian-type CagA *H. pylori* (Bhutan and Indonesia) than in those infected with Western-type CagA *H. pylori* predominant (Myanmar and Bangladesh). We found positive correlations between the anti-CagA antibody and antral monocyte infiltration in subjects from all four countries. There was no significant association between bacterial density and the anti-CagA antibody in the antrum or the corpus. The East Asian-type CagA ELISA had improved detection of the anti-CagA antibody in subjects infected with East Asian-type CagA *H. pylori*. The East Asian-type CagA ELISA should, therefore, be used in populations predominantly infected with East Asian-type CagA. © 2019, Springer-Verlag GmbH Germany, part of Springer Nature.

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