A New Rapid Diagnostic Test For Acute Dengue Infection

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Background/Objective

Early recognition of dengue is challenging because initial symptoms are often non-specific, viremia may be below detectable levels and serological tests confirm dengue usually late in the course of illness. There is an unmet need for specific, inexpensive dengue diagnostic tests that can be used for clinical management, surveillance and outbreak investigations. In previous studies, we found that NS1 binds to coagulation factor II (thrombin) and forms NS1-thrombin complex in dengue patients' sera. Higher sensitivity for detecting dengue infection is achieved by using anti-NS1 monoclonal antibodies to detect NS1-thrombin complex in dengue patients' sera. In the current study, we aimed to evaluate the accuracy of a new NS1-thrombin-based rapid diagnostic test for acute dengue infection compared to an established active comparator.

Method

Patients admitted for clinically suspected dengue infection to a tertiary medical center in Tainan, Taiwan were enrolled from September, 2014 to May, 2015. Serum/plasma was collected and then tested parallelly with the new kit and commercial comparator. The sensitivity and specificity of the kits were analyzed in comparison with the test results from central laboratories in Centers for Disease Control, Taiwan.

Result

Totally 220 dengue-positive specimen were included for analysis. In the pilot study with specimen obtained in the acute stage of dengue infection, the sensitivity of new dengue diagnostic kit was better than commercial reference kit (89.66% vs. 86.21%). The limit of detection (LOD) for the NS1-thrombin-based kit was 0.127 ng/mL, while the LOD of NS1-only kit was 0.187 ng/mL.

Conclusion

The new NS1-thrombin-based rapid dengue diagnostic test had higher sensitivity than common commercial kits. Further clinical trials are needed to validate its usefulness in acute dengue infection.