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Original Research Article

A Comparative Study on NS1 Antigen Detection in Acute Dengue Infection by Rapid Diagnostic Test and Elisa in a Tertiary Care Hospital

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Abstract:

Introduction: Dengue fever has emerged as a serious public health concern in India due to the high mortality and morbidity linked with it. It is the most frequent viral disease transmitted to people by mosquitos. As a result, early and rapid laboratory diagnosis of dengue fever is critical. The present study was done to compare Immunochromatography rapid diagnostic test (RDT) with Enzyme Linked Immunoassay (ELISA) for detecting Dengue virus NS1 antigen in patients of suspected of dengue illness

Materials and methods: This cross-sectional study was done on 100 clinically suspected cases of Dengue at a tertiary care hospital in Kadapa, Andhra Pradesh, India. All the sera samples were collected and subjected to NS1 antigen detection test by rapid test and NS1 ELISA and compared

Results: Out of total 100 samples, 74 samples tested positive by NS1 rapid test & 86 samples were tested positive by NS1 ELISA. The sensitivity, specificity of dengue NS1 antigen rapid test was 84.8% and 93% when compared to ELISA.

Conclusion: The NS1 ELISA test requires extra steps and time. RDTs take only roughly 15 to 30 minutes to complete in a single phase. Despite the fact that ELISA outperforms RDT, in nations with fewer infrastructures and in remote regions, RDTs are more useful for early diagnosis and management of dengue with less expertise in a short period of time.

Keywords: Dengue, NS1 antigen, Rapid test, Enzyme linked immunosorbent assay.

Introduction

Dengue is caused by one of four dengue virus serotypes (DENV-1, 2, 3, and 4). Dengue virus is a single-stranded, positive sense enveloped RNA virus in the Flavivirus genus [1]. Human dengue virus infection is frequently undetected, although it can cause a wide variety of clinical symptoms, from moderate fever to potentially lethal dengue shock syndrome. Many viral illnesses, including Japanese encephalitis (JEV), chikungunya (CHIKV), and West Nile virus (WNV), cause dengue-like sickness. As a result, clinically suspected and laboratory verified cases have two distinct implications [2].

Efficient and precise dengue diagnosis is critical for clinical care, including early detection of severe cases, case confirmation, and ruling out other possible diagnoses. It is also critical for disease surveillance and outbreak management. A rough timeline of primary and secondary dengue virus infections, as well as the diagnostic tools available to diagnose infection. [3].

The World Health Organisation (WHO) guidelines for dengue diagnosis in 2009 designated three diagnostic techniques as gold standards: viral isolation and identification, viral nucleic acid detection, and serological assays for IgM or IgG seroconversion. The current study compared the Immunochromatography rapid diagnostic test (RDT) with the Enzyme Linked Immunoassay (ELISA) for detecting Dengue virus NS1 antigen in patients suspected of having dengue disease.

Materials and Methods:

From July 2021 to November 2021, a prospective comparative study was carried out in the microbiology department at Fatima Institute of Medical Sciences, Kadapa. Before the study started, the Institutional Ethics Committee gave its approval. The subjects gave their informed consent before any kind of study began. In the case of a paediatric patient, parental consent was acquired.

Inclusion Criteria

- Clinically suspected cases of dengue presenting with fever from 1 to 4 days along with symptoms and signs of acute dengue like

illness and whom serological diagnosis requested for dengue infection.
- Patients of all age groups.

Exclusion Criteria

- Patients presenting with fever > 4 days.
- Non-conclusive reports, already diagnosed cases of dengue (referred or admitted with dengue positive report).

Type of Sample and Collection: After receiving written informed consent, a sample of 3 to 5 millilitres of blood was aseptically taken from clinically suspected dengue fever patients who visited the paediatric and general medicine outpatient departments within 4 days after the commencement of the illness. Furthermore, pertinent clinical, investigative, and demographic data was gathered from the patient's record file. In case record form, a thorough clinical history of the patient was documented along with pertinent information.

Sample Processing: Collected samples were centrifuged at 2500 rpm for 15 min to obtain serum and plasma. The sera were subjected to rapid dengue NS1 antigen test, and NS1 ELISA,

Rapid Dengue Non - Structural Protein - 1 Antigen Detection Test: Based on the immunochromatographic concept, a quick dengue NS1 antigen detection test was performed on a total of 100 samples. The operation was carried out in accordance with the manufacturer's instructions, and the outcomes were classified as either positive or negative.

Dengue non-structural protein-1 antigen detection enzyme-linked immunosorbent assay: NS1 antigen ELISA analysis was conducted on each of the 100 serum samples. The NS1 antigen J Mitra Co., ELISA kit was utilised. The test was conducted and the results interpreted precisely in accordance with the manufacturer's instructions. The ELISA reader was used to measure the O. D. at 450 nm.

Results

Out of 100 samples received in laboratory, 44 samples belong to Females & 56 samples belong to males (Table 1).

Table 1: Gender Distribution

sex	Number (n)	Percentage (%)
Male	56	56
Female	44	44

Out of total 100 samples, samples tested positive by ELISA test were 86% as shown in Table 2.

Table 2: NS1 Antigen detection by ELISA method

Findings	Positive	Percentage (%)
NS1 Positive	86	86
NS1 Negative	14	14

Out of total 100 samples, samples tested positive by RDT test were 74% as shown in Table 3.

Table 3: NS1 Antigen by RDT (Immunochromatography Card Method)

Findings	Positive	Percentage (%)
NS1 Positive	74	74
NS1 Negative	26	26

When the rapid ICT test for NS1 Ag was compared with the NS1 Antigen capture ELISA, it showed a sensitivity of 84.8% and specificity of 93% as shown in Table 4.

Table 4: Comparison of NS1 Rapid test and NS1 ELISA test

Parameter		NS1 ELISA		Sensitivity	Specificity
		Positive	Negative		
NS1 Rapid test	NS1 Positive	73	1	84.8%	93%
	NS1 Negative	13	13		

Discussion: There is no dengue vaccine available. Early identification and treatment are crucial in endemic areas for decreasing sequelae and disease control. Along with preventive issues, precise identification of dengue infection is difficult due to the lack of specific symptoms, particularly in the early stages. Dengue infection can be detected by virus isolation and viral RNA detection using RT-PCR, but these technologies are time consuming and not available in most tertiary care hospitals, therefore diagnosis relies on identifying dengue specific NS1 antigen using rapid kits or ELISA. In our study, the sensitivity of the quick ICT tests for NS1 Ag was 84.8% and the specificity was higher than 93% when compared to ELISA. If the tests are positive, the diagnosis of acute dengue infection is largely equivalent to that of ELISA-based testing. The outcomes of this study are similar with previous research that has indicated the effects of rapid ICTs [4-6]. The findings of Zainah et al. [7] demonstrate that the quick dengue NS1 antigen immune chromatography test apparatus performs

as anticipated. They advocate the use of quick Immunochromatography test equipment for diagnosing a population group characterised by clinical symptomatology of acute dengue infection due to its excellent specificity (99%) and positive predictive value (99.6%). In line with earlier investigations, our analysis found a greater specificity of 84.8% for NS1 ICT, as did Kulkarni et al., [8] and Chakraverti et al., [9].

Conclusion: The rapid RDT Kit used for NS1 antigen detection performed similarly to an ELISA-based test, according to the findings. Rapid dengue ICT assays can be used for early detection and management of acute dengue infection in countries lacking diagnostic laboratory infrastructure.

References

1. Pal, Subhamoy, et al. 2014. "Evaluation of Dengue NS1 Antigen Rapid Tests and ELISA Kits Using Clinical Samples." PloS one, 9(11): e113411
2. Capeding, Maria Rosario, Z., et al. 2015. "Laboratory-Confirmed Dengue in Children in Three Regional Hospitals in the Philippines in 2009−2010." The Pediatric Infect. Dis. J., 34(11): 1145–51.
3. WHO. 2009. "Dengue: Guidelines for Diagnosis, Treatment, Prevention, and Control." Special Programme for Res. Training in Trop. Dis., 147.3
4. Pal, Subhamoy, et al. Evaluation of Dengue NS1 Antigen Rapid Tests and ELISA Kits Using Clinical Samples. PloS one, 2014; 9(11): e113411.
5. Groen, Jan, et al. Evaluation of Six Immunoassays for Detection of Dengue Virus Specific Immunoglobulin M and G Antibodies. Clin. Diag. Lab. Immunol.2000; 7(6): 867–71.
6. Shih, Hsin-I et al., Applications of a Rapid and Sensitive Dengue DUO Rapid Immuno chromatographic Test Kit as a Diagnostic Strategy during a Dengue Type 2 Epidemic in an Urban City. PloS one, 2016; 11(7): e0158437.
7. Zainah S, Wahab AHA, Mariam M, Fauziah MK, Khairul AH, Roslina I, et al., 2009. Performance of a commercial rapid dengue NS1 antigen immunochromatography test with reference to dengue NS1 antigen-capture ELISA. J Virol Methods, 155:157-160.
8. Kulkarni RD, Patil SS, Ajantha GS, Upadhya AK, Kalabhavi AS, Shubhada RM, et al., 2011. Association of platelet count and serological markers of dengue infection – importance of NS1 antigen. Indian J Med Microbiol, 29(4):359-62.
9. Chakraverti TK, Malkappa SK and Saileea K, 2012. Comparison of diagnostic efficacy of NS1 antigen based immunochromatographic test with immuno-sorbent assay and its role in detection of early dengue infection. J Evol Med Dental Sci, 1(6):1071-1075.