



A COMPARATIVE STUDY OF DENGUE RAPID IMMUNOCHROMATOGRAPHIC CARD TEST WITH DENGUE ELISA AT TERTIARY CARE CENTRE, SOUTHERN RAJASTHAN.

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ABSTRACT

Introduction: Dengue has emerged as a major public health concern throughout India because of the mortality and morbidity associated with it. Hence, early and rapid laboratory diagnosis of dengue is crucial. This study was aimed to compare results of immunochromatographic card test and ELISA in dengue fever patients at a tertiary hospital.

Materials & Methods: Blood samples from the clinically suspected cases of Dengue were collected using strict aseptic precautions and serum was separated using standard methods. Serum collected was tested for NS1 antigen and IgM/IgG antibodies using one-step immunochromatographic assay. All rapid card test positive samples were retested by IgM and NS1 ELISA. Specificity, sensitivity, positive predictive value (PPV) and negative predictive value (NPV) of the IgM and NS1 rapid ICT test were calculated by using IgM and NS1 ELISA results as the reference test.

Results: From April 2023 to September 2024, a total of 318 samples were found to be positive for dengue serology for one or more parameters. The most affected age group was 21–30 years (26.7%). Males were affected more than females. Maximum number of patients were reported in month of October (32.4%) followed by September (19.5). Sensitivity, specificity, PPV, NPV and accuracy of NS1 rapid test kits were 97.01%, 100%, 100%, 95.1% and 98.1% respectively and for IgM rapid test kits was 96.7%, 100%, 100%, 97.1% and 98.4% respectively.

Conclusions: Although ELISA is gold standard test but high sensitivity and specificity of rapid kits also helps in early screening of patients and can further limit the spread of disease.

Keywords: Dengue, Public health, Endemicity, Rapid diagnostic test, ELISA, Early detection, Screening

Introduction

Dengue has emerged as a major public health concern throughout India because of the mortality and morbidity associated with it. It is the most common mosquito-borne viral disease of humans. Hence, early and rapid laboratory diagnosis of dengue is crucial. (1) Presently, the basic methods used by most laboratories for the diagnosis of dengue virus infection include viral isolation, detection of

viral genomic sequence by nucleic acid amplification technology assay (RT-PCR), Antigen detection, particularly non-structural protein 1 (NS1) and the detection of dengue virus-specific IgM antibodies by the IgM-capture enzyme linked immunosorbent assay (MAC-ELISA) and/or the rapid dengue immunochromatographic test (ICT).³ Out of these, virus isolation and nucleic acid amplification tests require expertise, expensive equipment's and reagents and time delay. So, detection of NS1 antigen and IgG/IgM antibody is an easy and cheaper for diagnosis of dengue infection. Immunoassays for NS1 and IgM offer a convenient format for dengue diagnosis, and several ELISA and rapid diagnostic tests are commercially available (2). In present study we aimed to compare results of immunochromatographic card test and ELISA in clinically suspected dengue fever patients at a tertiary hospital.

MATERIALS AND METHODS

This hospital based study was conducted from April 2023 to Sep 2024. Consent were taken from all the patients. Study was approved by the institution ethical committee of Pacific Medical College and Hospital, Udaipur, Rajasthan, India.

Blood samples from the clinically suspected cases of Dengue were collected from outpatient department as well as patients admitted in different clinical wards of Pacific College and Hospital Udaipur. Processing of samples was done at Department of Microbiology, Pacific Medical College and Hospital, Udaipur, Rajasthan, India.

3-5 ml of blood was collected from each patient using strict aseptic precautions and serum was separated using standard methods. Serum collected was tested for NS1 antigen and IgM/IgG antibodies using one-step immune-chromatographic assay (Dengue Rapid IgM/IgG test and NS1 test by SD BIOLINE) as per the manual provided with the test kit. All rapid card test positive samples were retested by IgM and NS1 ELISA as per the manual provided with the test kit (by using kit of J. Mitra & Co. Pvt. Ltd).

STATISTICAL ANALYSIS: Data were entered into Microsoft Excel. Descriptive statistics such as percentages were used. Specificity, sensitivity, positive predictive value (PPV) and negative predictive value (NPV) of the IgM and NS1 rapid ICT test were calculated by using IgM and NS1 ELISA results as the reference test.

RESULTS

From April 2023 to September 2024, a total of 318 samples were found to be positive for dengue serology for one or more parameters. The most affected age group was 21–30 years (26.7%) followed by 11–20 years (19.2%) (FIG1). Out of 318, 181 (56.9%) were males and 137 (43.1%) were females (FIG2). Maximum number of patients were reported in month of October (32.4%) followed by September (19.5) (FIG3).

Of 318 seropositive cases, 160 (50.3%) individuals were positive only for NS1 antigen, 110 (34.6%) were positive for only IgM antibody, 8 (2.5%) were positive for only IgG. 27 (8.5%) were positive for NS1 and IgM, 3 (0.9%) were positive for NS1 and IgG, 5 (1.6%) were positive for IgM and IgG. 5 (1.6%) individuals were positive for all the three markers (FIG4).

Out of 318 samples, a total of 195 samples tested positive by NS1 antigen card test (61.3%) and 201 samples tested positive by NS1 ELISA (63.2%). Similarly, a total of 147 samples tested positive by IgM antibody card test (46.2%) and 152 samples tested positive by IgM ELISA (47.8%). Sensitivity, specificity, PPV, NPV and accuracy when only NS1 was considered on rapid test kits when compared with ELISA were 97.01%, 100%, 100%, 95.1% and 98.1% respectively. Sensitivity, specificity, PPV, NPV and accuracy when only IgM was considered on rapid test kits when compared with ELISA were 96.7%, 100%, 100%, 97.1% and 98.4% respectively (TABLE1).

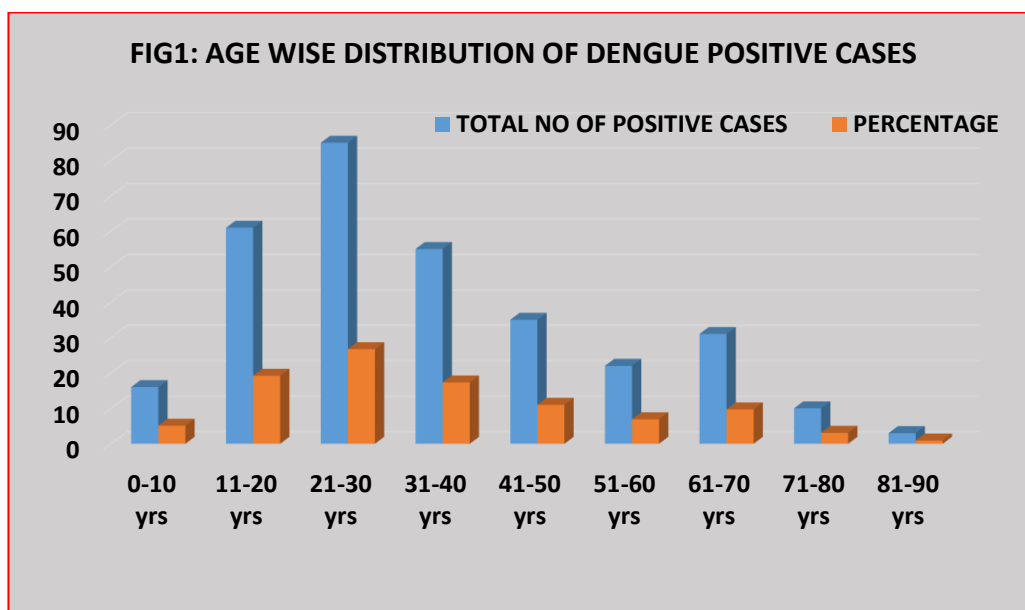


FIG 1: AGE WISE DISTRIBUTION OF DENGUE POSITIVE CASES

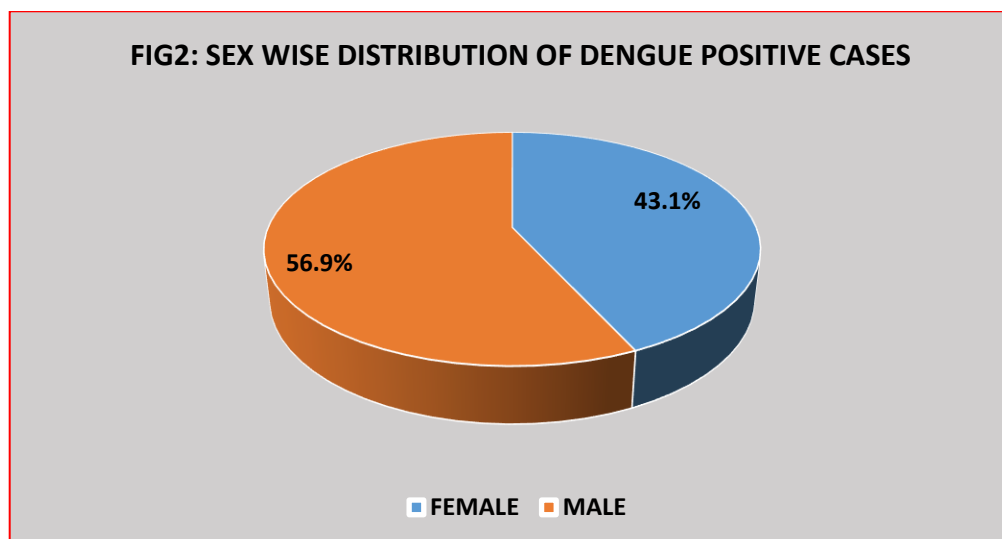


FIG 2: SEX WISE DISTRIBUTION OF DENGUE POSITIVE CASES

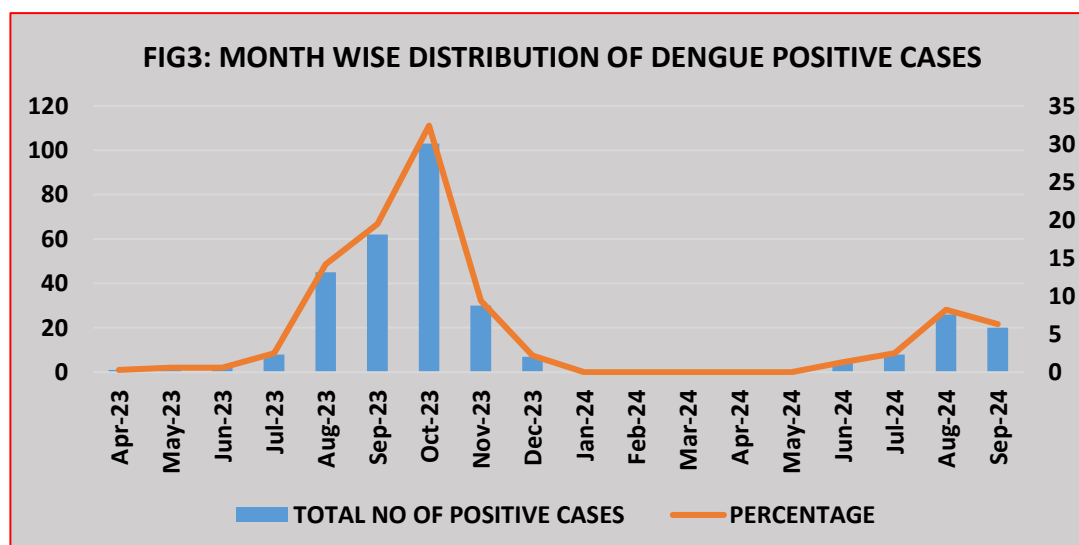


FIG 3: MONTH WISE DISTRIBUTION OF DENGUE POSITIVE CASES

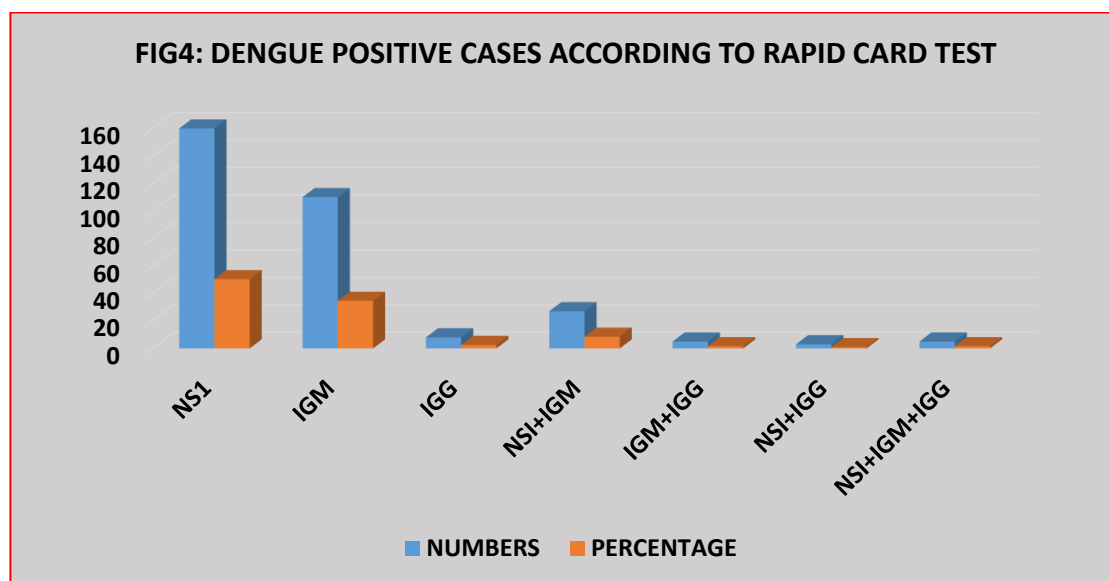


Fig 4: Dengue Positive Cases According To Rapid Card Test

Table1: Comparison Of Sensitivity, Specificity, Ppv And Npv Of Elisa With Rapid Ict Test

ANTIGEN/AN TIBODY	RAPID CARD POSITIVE	ELISA POSITIVE	SENSITIVIT Y	SPECIFICITY	PPV	N P V	ACCURACY
NS1	195	201	97.01%	100%	100%	95.1%	98.1%
IGM	147	152	96.7%	100%	100%	97.1%	98.4%

DISCUSSION

Dengue is an upcoming and swiftly spreading vector borne disease that has taken strong hold in India. Owing to the complicated interplay between the host, agent, vector, and environmental conditions, the number of cases in India has consistently increased substantially over the past ten years. It is now even considered as a hyper endemic disease in certain parts of India. (3)

In present study, the most affected age group was 21–30 years (26.7%) followed by 11–20 years (19.2%). Adolescents and young adults were at higher risk of developing dengue. Similar trend has been observed in study by Sumita Rajeevan *et al* (4), Sarah Hassan *et al* (5), Rajeshwari K G *et al* (2), Raji T.K *et al* (6), Samina Kausar Tabassum *et al* (1) where most affected age group was 21–30 years.

In present study, male were affected more than females. Similar findings were reported from other studies like Bharat Singh *et al* (7), Lakshmi *et al*. (8), Kalaivani *et al*. (9).

Combined, the age and sex distribution findings could be attributed to the complex interplay between outdoor nature of work (among men), dressing patterns (among women) and diurnal feeding habits of *Aedes aegypti*. (3)

In present study we evaluate the seasonal variation on a monthly basis. There was gradual increase in cases following July with a peak in October (postmonsoon period). This was similar to study by Dharendra Kumar Pandey *et al* (10), Hari om trivedi *et al* (11), Mathur S *et al* (12), Palewar MS *et al* (13). It may be because; this season is favourable for high breeding of vector mosquitoes. In udaipur, rainy season starts around late June and last till september. Rain, temperature and relative humidity are reported as the major and important climatic factors.

In present study, Sensitivity, specificity, PPV, NPV and accuracy of rapid test kits were 97.01%, 100%, 100%, 95.1% and 98.1% for NS1 and 96.7%, 100%, 100%, 97.1% and 98.4% for IgM. In this study high sensitivity and specificity of rapid diagnostic tests for early detection of dengue was observed. Similar results were also observed in study by Sarah Hassan et al (5) and Samina Kausar Tabassum1 et al (1).

CONCLUSIONS

Dengue remains to be a major public health problem in this part of the globe, affecting mainly the working age group. Moderate cases throughout the year and reaching at peaks during postmonsoon period have proved its endemicity in our region. High sensitivity and specificity of rapid diagnostic tests for early detection of dengue was observed. ELISA is a gold standard test but these kits are highly suitable for early detection of positive cases, especially in centres where facilities for ELISA are not available. As with high sensitivity and specificity it can help in early screening of patients and can further limit the spread of disease.

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