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Original Research Article.

A Comparative Analysis of Rapid Immunochromatographic Card Test with MAC –ELISA Used in Detection of Dengue at a Tertiary Care Hospital in Jamshedpur, Jharkhand

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ABSTRACT

Introduction: Dengue virus transmitted by mosquitoes is widely distributed throughout the tropics and subtropics. It is one of the most rapidly spreading mosquitos borne viral disease in the world. In India specially, dengue has emerged as a matter of major concern because of its epidemic proportions. Therefore, early diagnosis for dengue is called for, to reduce the mortality and morbidity attributed to it.

Aims and Objective: There are numerous methods for the diagnosis of dengue of which the serological tests play a significant role. Various rapid ICT tests are being used in the laboratories for the early diagnosis of dengue these days. The present study aims to evaluate the performance of rapid ICT with reference to MAC-ELISA for its role in diagnosis of dengue.

Methods and Materials: In the present study 305 suspected samples of dengue were collected during the month of October 2017 to December 2017. All the samples were collected by aseptic techniques.

Results: 92 samples were positive by Mac Elisa IgM Ab test. The prevalence of the disease was 30.16 %. When ICT IgM Ab test was compared with Elisa IgM capture Ab test a sensitivity of 95.65 % and specificity of 98.59 % was observed.

Conclusion: The high sensitivity and specificity makes it suitable to be used in acute diagnosis of dengue but Mac Elisa IgM capture Ab test combination will make it more reliable and confirmatory.

Keywords: Dengue Fever, ICT, IgM Antibodies, MAC ELISA.

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INTRODUCTION

Dengue fever is caused by an arbo virus of family Flaviviridae, genus flavi virus. It is a single positive stranded RNA virus and is transmitted from person to person principally by the bite of female Aedes mosquito which itself contracts the virus while feeding on the blood of infected individuals. Aedes aegypti and Aedes albopictus are the two most important vectors of Dengue. Dengue virus has four serotypes DEN-1, DEN- 2, DEN -3, DEN – 4. Infection with any one serotype confers lifelong immunity to that serotype. Secondary infection with Dengue serotype 2 or multiple infections with multiple serotypes lead to severe form of Dengue DHF/DSS.[1] Dengue in India was first reported during 1956 from Vellore district in Tamil Nadu. The first Dengue haemorrhagic fever (DHF) occurred in (Calcutta—West Bengal), in 1963 with 30% of cases showing haemorrhagic manifestations.[2] The patients with dengue fever presents typically with high grade fever, headache, retro orbital pain, photophobia, lymphadenopathy accompanied by facial flushing skin, erythema pain in the back and limbs. The severe forms of dengue fever are dengue haemorrhagic fever (DHF) and dengue shock syndrome (DSS) where there are chances of plasma leaking, fluid accumulation, respiratory distress, severe bleeding or organ impairment.[3]

Dengue is one of the vector-borne viral disease prevalent worldwide.[3] During the last half a century the incidence of dengue has increased by 30 folds and expanded to many other countries. The vector control effects are failing in urban areas also which is reflected as rapid yearly rise in the number of dengue cases and spread to sub-urban and rural areas.[4] Hence to reduce the high mortality and morbidity, early lab diagnosis and treatment of dengue fever is required. Acute dengue infection can be diagnosed by various methods which include virus isolation, viral nucleic acid detection, serological test for antigens, antibodies or combination of these techniques (WHO 2009).[5] These methods have their own advantages and disadvantages. The gold standard

test in the lab diagnosis of dengue infection are viral isolation or molecular methods (Lakshmi et al).[6] These tests are not only expensive, but needs technical expertise. Moreover the first two methods are time consuming and costly hence the diagnosis of dengue is mainly based upon the detection of dengue specific antibodies and/or NS1 antigen.(Kumaraswamy V et al; 2011).[7] Serological tests are ELISA based, ICT based tests etc. In those laboratories where the resources are limited, rapid immunochromatograhy, ICT based tests are being performed for the detection of NS1 Ag and IgM / IgG Antibodies for dengue. Though according to the guidelines of National Vector Borne Disease Control Programme; 2008, IgM antibody capture Elisa should be considered as diagnostic test for dengue infections which will help in early diagnosis of dengue.[8] The advantage of immunochromatography tests over ELISA is that it can be performed in small laboratories with limited infrastructure, skill and facilities. It also detects the presences of NS-1 antigen (non-structural protein 1) which is a glycoprotein that is produced in the early stage of infection and can be detected in the serum or plasma of patients (Shan et al 2015).[9] Diagnosis of dengue at an early stage is the only effective way to control the disease progression.

AIMS AND OBJECTIVES

Dengue is a major threat for public health, hence early diagnosis and control is warranted for. For early diagnosis of dengue virus infection various rapid immunochromatography tests are being performed these days.

The objective and aim of the test is to evaluate rapid immunochromatography test and compare it with ELISA capture IgM antibody test. The demographic profile of dengue fever was also observed.

MATERIALS AND METHODS

The present study was carried out in the department of microbiology, MGM Medical College & Hospital, Jamshedpur from the month of Oct 2017 to Dec 2017. This period was selected because just after the rainy seasons the no of dengue cases rises as seen according to previous year's records.

The patients were from the Jamshedpur and surrounding areas. A total of 305 suspected blood samples were collected under aseptic precautions. Serum was separated and subjected to SD Dengue NS1 Ab combo (bio –line dengue duo). This is immunochromatographic one step assay designed to detect dengue virus NS1 antigen and deferential IgM / IgG antibodies to dengue virus.

The MAC ELISA test was also performed which was manufactured by Arbodiagnotics and supplied by NIV Pune. The tests were performed according to kit manufacturer's instructions.

RESULTS AND DISCUSSION

In this study a total of 305 clinically suspected samples for dengue infection were evaluated and tested. 92 samples were reactive for Elisa IgM antibodies. These samples were taken as confirmed cases for dengue virus infection. Of the 92 samples 55 samples were of males. The no. of female positive samples was 37. Number of patients suffering from dengue virus was more in the age group 21-30 years NS1antigen by rapid ICT was positive in 98 cases.

Table 1: Gender wise distribution of Dengue positive cases by ELISA IgM capture Ab test:

Sex	n	%
Male	55	59.78
Female	37	40.22
Total	92	100

Table 2: Age wise distribution of dengue positive cases by ELISA IgM capture Ab test:

Age group (Years)	n	%
01-10	3	3.26
11-20	21	22.83
21-30	26	28.26
31-40	20	21.34
41-50	10	10.87
51-60	08	8.70
61-70	04	4.35
>/ 70	00	0
Total	92	100

Table 3: Comparison between ELISA IgM capture Ab and ICT for IgM Ab:

	ELISA Positive IgM Ab test	ELISA Negative IgM Ab test	Total
ICT IgM Positive	88	03	91
ICT IgM Negative	04	210	214
Total	92	213	305

Sensitivity = 95.65%; Specificity = 98.59 %; PPV = 96.70 %; NPV = 98.13 %

The analysis of the study shows the prevalence of the disease to be 30.16%. These cases were confirmed cases positive by IgM ELISA capture antibody test. The prevalence of the disease was more in males in comparison with females and the age group in which the cases showed predominance was the age group between 21 to 30 yrs. (28.26%). These findings were similar to studies conducted by Tabasum et al 2013[2], Sarah et al 2018[3], Reddy et al. 2016[10], Srivastava A, Dash PK et al 2017.[11] The result of the comparisons between rapid ICT test for IgM antibody with IgM capture ELISA ab test. The ICT showed sensitivity of 95.65% and specificity of 98.59%. The positive predictive value 96.70%. NPT was 98.13%. These findings were consistent with findings of other studies which have shown the positive predictive value of rapid immunochromatographic tests to be more than 85% (Reddy et al 2016).[10] Similar result in which ELISA had higher detection power was observed by Sarah et al.[3]

The ICT test had good specificity i.e. 98.59%. The rapid diagnostic tests are highly suitable for early detection of positive cases as with high sensitivity and specificity, it can help in early screening of patients and can further limit the spread of disease.[3] Since the sensitivity and specificity of various kits in the market in a developing country like India varies widely and this needs to be kept in mind while choosing and performing the dengue diagnostic

test and an initial validation of the rapid kits will definitely help (Reddy et al 2016).[10]

The rapid ICTs have a major advantage that they are easy to perform; they need less expertise and can be done within minutes (Chatterjee et al).[12]

CONCLUSION

Dengue has emerged as a major challenge for public health in both urban and rural areas, so to combat the severity of the disease major interventions are required at an early stage to lessen the mortality and morbidity and also for the control of the disease. Various laboratories are using rapid immunochromatography test for the early diagnosis of dengue. The rapid ICT test can be used as screening as they are less cumbersome, easy to perform cost effective, can be performed in laboratories which are not equipped with ELISA based equipment's like ELISA reader and washer. There is no need to collect the samples together for testing as a single sample can be run. It also detects the NS1 Ag as well as IgM/IgG Antibody. NS1 Antigen is detected in the early phase of disease and thus helps in early detection of positive cases. Dengue IgM Ab can be detected from as early as 3 days to 60 days of infection. The ICTs also have an added advantage of being able to be used in remote and rural areas. But, its sensitivity and specificity can be increased by ELISA based studies. Hence, for accurate and early diagnosis of dengue it can assist MAC ELISA Ab test as single test are not so reliable.

As dengue cases are showing rising trends so active surveillance is required for and appropriate control measures is the hour of need. Early diagnosis and early treatment is the main stay in the management of dengue cases.

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