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Comparison Of Diagnostic Performance Of Different Kits For Detection Of Acute Dengue Infection During An Outbreak In Lakhimpur District Of Assam

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Abstract:
Background: Now a day's dengue becomes an epidemic in almost all over the India covering 80% districts in Assam. The study was carried out at lakhimpur district of Assam which is a place considered to be the 'Gateway to Arunachal Pradesh and important for transport and communication.
Objectives: The aim of the study was to find out the diagnostic performance of different commercially available kits for early detection of dengue infection during an outbreak.
Methods: Dengue NS1 an IgM card test was done to detect acute dengue infection in all the collected samples (SD Bioline Dengue duo Dengue NS1 + Ab Combo). IgM Mac Elisa Test was used as a gold standard method.
Result: Out of 340 nos of clinically suspected dengue patients, SD BIOLINE Dengue Duo kit showed 89 cases were found Dengue IgM positive and 142 nos were Dengue NS1 positive. Whereas only 47 nos of samples were found to be positive in Dengue IgM Elisa test and 13 nos was Dengue NS1Ag Elisa positive. All the NS1Ag Elisa positive samples were found Dengue IgM Elisa positive. Adult males are more affected with dengue. More nos of dengue cases were reported from urban area as compared to rural. All community has equally affected with dengue infection. Economically backward people are more pretentious to dengue infection. The sensitivity and specificity of SD BIOLINE Dengue Duo kit was 95.92% and 22.50% respectively.
Conclusion: It is accomplished that in further study, for early detection of acute dengue infection not only SD BIOLINE Dengue Duo kit but also Elisa technique should also be require for strong evidence.

Keywords: Dengue, SD BIOLINE Dengue Duo kit, Elisa, Sensitivity, Specificity.

INTRODUCTION:

Dengue (DEN) fever also known as breakbone fever is an infectious mosquito borne tropical disease caused by the dengue virus (DENV).There are four strains of the virus, which are called serotypes, and these are referred to as DENV-1, DENV-2, DENV-3 and DENV-4 [1]. Dengue is endemic in more than 110 countries [2]. It infects 50 to 100 million people worldwide a year, leading to half a million hospitalizations, [3] and approximately 12,500–25,000 deaths [4, 5]. In India, the first evidence about the occurrence of dengue fever was reported during 1956 from Vellore district in Tamil Nadu. The first DHF outbreak occurred in Calcutta (Kolkata, West Bengal) in 1963 with 30% of cases showing haemorrhagic manifestations [6].

In Assam dengue confirmed cases were first reported by Regional Medical Research Centre, ICMR, Dibrugarh Assam, in 1992 and cases were reported from Dibrugarh, Dhemaji, Lakhimpur and Golaghat districts.The neighbouring state Nagaland also experienced a similar outbreak in the year 2009. In the subsequent years, 2008 and 2010, Assam also reported the occurrence of dengue outbreak with involvement of all the four dengue virus serotypes [7]. It is observed that more than half of this region is affected in these outbreaks. There is every possibility of spreading of Dengue to rest of the region as frequent movement of people within the states of the region can trigger further transmission of the disease. Moreover, from the tourism point of view also this region attracts many people from the other parts of the country. Entomological survey also indicates that the presence of dengue vectors in this region [8].

As we know that now days, dengue is spreading rapidly to newer areas with outbreaks occurring more frequently and explosively in different parts of India including this part of the country as well. In the previous year 2012, dengue was also epidemic in almost all districts of Assam affecting thousands of people. So, it is necessary to detect acute dengue infection as soon as the virus enter in human body by which further transmission can be prevented. At this stage easy and less time consuming method is required for early detection of acute dengue infection which

helps in taking appropriate control measure and preventing an impending outbreak in time. Now a day's health staffs were used different types of Rapid diagnostic kits in the field for early detection of infectious diseases like dengue, but it is important to be acquainted with the diagnostic performance of the kits. It is also important to mention that till date no curable effective vaccine has been licensed so in this regard prompt and accurate diagnosis is the effective tool. Keeping in view of the above fact the study is carrying out to see the diagnostic performance of routinely available kit for detection of acute dengue infection.

The study was conducted to find out the prevalence of dengue cases in this part of Assam as well as to know the Sociodemographic, clinical and economic status among the dengue patients. Age wise distribution of the dengue patients was also studied to know that if any shifting of ages takes place based on previous study. Travel status of the patient was also recorded to find out the source of transmission. The study also mapped out high risk areas of dengue in lakhimpur district of Assam. Community wise distribution of dengue cases was also observed during the study. Hematological study was also carried out to know the role of different hematological parameters associated with dengue fever.

STUDY AREA:

In 2012, an outbreak of Dengue affected 24 (Twenty four) district in Assam and most of the dengue positive cases were reported from Kamrup and Lakhimpur district. Lakhimpur District covered an area - 2,277 km2, with a total population -1,040,644 (according to 2011 census) which is located on the north eastern corner of Assam. Lakhimpur district lies between 26°48′ and 27 °53′ northern latitude and 93 °42′ and 94°20′ eastern longitude approximately. North Lakhimpur is a very important town in terms of transport and communication, which is considered to be the 'Gateway to Arunachal but it may become the reason of transmission of dengue infection from different parts.

MATERIALS AND METHODS:

Two ml of blood/CSF samples were collected from Dengue suspected patients admitted at different health centers of Lakhimpur district in Assam as well as by household visit to the affected area. Initially Dengue NS1 an IgM card test was done to detect acute dengue infection (SD Bioline Dengue duo Dengue NS1 + Ab Combo). IgM Mac Elisa (NIV Pune) test was used as a gold standard method for further confirmation. The test was done at district priority laboratory of North Lakhimpur Civil Hospital. All age group and both the sexes were included in the study. Total population from all Block PHC under Lakhimpur district were collected and based on that IRs was calculated. Time, place and person analysis was done.

The SD BIOLINE Dengue Duo kit is a rapid, an in-vitro immunochromatographic, one step assay designed to detect both dengue virus NS1 antigen and qualitative and differential test for the detection of antibodies to Dengue virus (Dengue IgG/IgM) in human serum, plasma or whole blood. The sensitivity and specificity of SD BIOLINE Dengue Duo (Both NS1 and IgG/IgM) is 84% and 98% respectively according to the kits instruction. Whereas Dengue IgM Mac Elisa kit is used for the qualitative detection of IgM antibodies to dengue antigen in human serum/CSF sample. The sensitivity and specificity of Dengue IgM Capture Elisa kit (NIV Pune) is 98.15% and 96% respectively.

RESULT:

A total 340 (Three hundred and fourty) nos of clinically suspected dengue cases were examined by rapid SD BIOLINE Dengue Duo kit for detection of Dengue NS1 antigen and IgG/IgM antibodies from human serum sample. Out of which 89 (eighty nine) nos of samples were found Dengue IgM positive and 142 (One hundred and fourty two) nos of samples were found Dengue NS1 positive. All the dengue IgM/NS1 positive and some of Dengue IgM /IgG/NS1 negative samples were screened to detect Dengue IgM antibodies by using Enzyme linked immunosorbent assay (Elisa) technique for further confirmation.47 (Fourty seven) nos of samples were found to be positive in Dengue IgM Elisa test and 13 (Thirteen) nos of samples were Dengue NS1Ag Elisa positive. All the NS1Ag Elisa positive samples were found Dengue IgM Elisa positive. In this study IgM Elisa technique was used as a gold standard for diagnostic purpose and to compare the diagnostic performances of SD BIOLINE Dengue Duo kit.

The diagnostic performance of SD BIOLINE Dengue Duo kit was calculated. Using Elisa as a gold standard method it was found that the sensitivity and specificity of SD BIOLINE Dengue Duo kit was 95.92% and 22.50% respectively. Positive predictive value and Negative predictive value of the kit was found as 60.26% and 81.82%.At 95% Confidence interval the positive likelihood ratio was 1.12 and negative likelihood ratio was 0.18. Prevalence of dengue among the population in lakhimpur district was found as 55.06%.

Demographic characteristics among dengue positive cases showed that adult males are more affected (Table 1). More nos of Dengue positive cases were reported during the month of October (Fig 1). Among the dengue positive patients it was observed that all patients (100%) had fever. The least common symptoms were fever with vomiting, hematuria and chill (2.13%).74.46% had fever with body pain (Fig 2). 67% of the affected patients was economically backward and they income from different sources like driving, daily worker etc . 21.27% of the dengue positive patients had a travel history of outside the local area. The Incidence rate of dengue was more in Bihpuria block PHC and Town areas of Lakhimpur district (Fig 3). Community wise data revealed that all the community groups are almost equally affected with dengue in. Ahom, Brahmin and Kachari community group are more affected (Fig 4).

Result obtained from homological study it was found that majority of dengue positive patients had thrombocytopenia. Some of affected patients had leukocytopenia, leukemia, lymphoma, Monocytosis.

DISCUSSION:

The first dengue IgM positive case was reported on 27 th September, 2012 and it was reached a peak level during

the month of October and then slowly declined in the month of November. The last positive case was reported on 14 th November, 2012. Demographic data revealed that the initial cases reported from Singia village under Laluk PHC which is approximate 20 km apart from Arunachal Pradesh. After taking the patients detail history it was confirmed that he has a travel history to Itanagar before 2 (two) days on the onset of the fever. There is an every possibility of spreading of Dengue viruses from the nearby state as recent dengue outbreak has been reported from that state. Another reason is the frequent migration of the people from this area to other district for different purposes. Few days after the occurrence of dengue cases it was found that most of the dengue positive patients show no travel history outside the local area during last one month which was an indication of persistance of Dengue viruses in this area. Analysis of surveillance data indicated that most nos of dengue positive cases were reported from Assam-Arunachal border areas of Laluk, Harmutty and Banderdewa where dozens of people were get together for different purposes. Majority of positive cases were also reported from town area. Active surveillance was done which showed that in urban areas, standing water in water coolers is one of the most common breeding grounds for mosquitoes which cause dengue. Water stored in flowers pots in urban areas, too, are breeding ground for mosquitoes. During the study it was observed that SD BIOLINE Dengue Duo kit gives some false positive result in our study. Keeping in view of the above fact the diagnostic performance of the above rapid diagnostic kit was calculated by using formula's based on Bayes' theorem. Although SD BIOLINE Dengue Duo kit is a rapid and less time consuming method for early detection of dengue infection but the kit shows less specificity as compared to Elisa. Whereas the kit shows excellent sensitivity in detection of acute dengue infection. Some of the study revealed that simultaneous detection of NS1/IgM/IgG would be potentially useful for dengue diagnosis in both endemic and non endemic areas [9, 10, 11] but our result gives somewhat different issue. Further studies will required to assess the performance and impact of early laboratory diagnosis of dengue in the routine clinical setting. It can be used in combination with the MAC Elisa for case detection and as screening test.

The age group of 20-40 years was highly affected with dengue which is consistent with the outbreak in Assam in 2010 [12, 13]. In some parts of the world, it is mainly a pediatric public health problem [14]. It is attributed to the changes in locations where disease transmission takes place. The higher prevalence of dengue infection was noted among male patients than female patients unlike other reports in which both the sexes were equally affected [13, 15]. The male-to-female ratio was 3.27:1 which is comparable with the study in other parts of Assam (Gupta E et al.,2005,nvbdcp.gov.in/mp-assam.html4) Male preponderance and the age group of 20-40 years indicate more transmission of dengue infections at work sites.

CONCLUSION:

Dengue cases were more during September to November in the postmonsoon season which is useful to plan special preventive strategies. The study draws attention toward the male, young adult age group. Dengue infection is no more an urban area infection but it has penetrated in rural areas also. As SD BIOLINE Dengue Duo kit gives less specificity but excellent sensitivity it cannot be used alone for early detection of acute dengue infection.

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Table and Figures:

Table 1: Demographic characteristics among the dengue IgM Elisa positive cases

Demographic characteristics		Nos of Dengue IgM Elisa positive cases
Age group	0 to 10	2
	11 to 20	4
	21 to 30	19
	31 to 40	16
	41 to 50	3
	51 to 60	2
	>60	1
Sex	Male	36
	Female	11
Total		**47**

Fig 1: Nos of Dengue positive cases by months in lakhimpur district of Assam in 2012

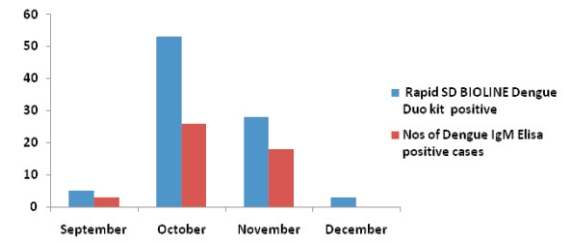

Fig 2: Frequency of selected symptoms among patients with dengue fever in Lakhimpur district of Assam, 2012 (n=47)

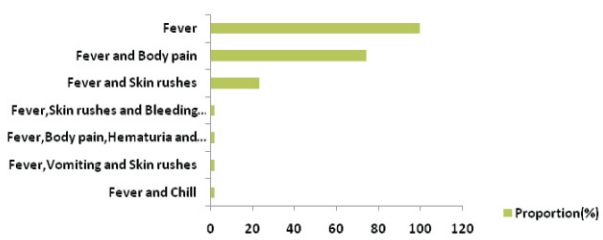

Fig 3: Incidence of Dengue in different areas of Lakhimpur district in Assam, 2012

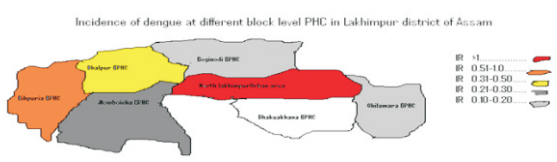

Fig 4: Community wise frequency of dengue IgM Elisa positive cases in lakhimpur district of Assam