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Evaluation of rapid immunochromatographic test for the early diagnosis of dengue virus infection and their comparative study by IgM capture Elisa in Tertiary Care Hospital, at PMCH, Patna

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Abstract: Objective: The aim of present study was conducted to evaluate the rapid immunochromatographic tests that detect NS_1antigen, IgM, IgG antibody simultaneously and their comparative study by IgM capture Elisa. ***Material and methods***: A total of 368 clinically diagnosed patients of dengue fever were included in the study. From all the patients 368 blood samples were collected and serum were separated. From all the serum tests were performed by rapid immunochromatographic test kit which can detect all three parameter NS_1Ag, IgM& IgG antibody according to packet insert by manufacturers guide lines. All the tests were compared by IgM capture Elisa. ***Result:*** Out of368 blood samples of dengue fever 136 samples were positive by rapid immunochromatographic test. Among 136 positive cases 127 cases were NS_1Ag positive,05 cases are IgM reactive; 03 samples are IgG reactive and only 01 samples are reactive forNS_1, IgM & IgG. Out of 368 blood samples tested by dengue Ig M capture Elisa only 123cases (33.42%) were reactive. ***Conclusion***: Detection of dengue NS_1Ag in the patient can be used as screening test in early cases of dengue illness. Since it is easy to perform it can be used in primary health care centres to take appropriate measure to reduce morbidity and mortality. Early notification of disease can awake the public health authority to take control measures.

Keywords: Rapid immunochromatographic tests (ICT), Elisa, dengue fever.

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INTRODUCTION

Dengue virus is a flavivirus found in tropic and sub tropics. Four serotype of virus (DEN 1to 4) causes human diseases. These are closely related but antigenically distinct. Dengue virus is transmitted by mosquito aedes agypti[5].Disease may be present with a range of clinical syndrome as acute undifferentiated febrile illness characterised by mild to high grade fever lasting 3 to 7 days, severe headache, backache, body ache, retro-orbital pain along with muscle and joint pain and rashes. The severe form of disease is dengue haemorrhagic fever and dengue shock syndrome[3].

Dengue virus is envelope positive sense of RNA virus. The genomic RNA is composed of three structural protein gene that encode for nucleocapsid or core protein (C) a membrane associated protein, an envelope protein(E)and seven non-structural (NS) proteinincludingNS_1 gene. Among non-structural protein NS_1 is highly conserved glycoprotein which appears essential for viral Replication. During acute phase of viral illness NS_1 circulate in patient sera.

Early diagnosis of disease is important to forecast the warning of an epidemic and to take appropriate measure for vector control. There are two main method for diagnosing dengue infection namely virus and antibody detection. Virus detection includes viral isolation, polymerase chain reaction (PCR) and detection of non-structural protein (NS_1) antigen[8]. Antibody detection includes hemagglutination inhibition (HAI) and detection of IgM and IgG antibodies[2].

Dengue specific IgM can be detected in blood usually 3-5 post onset days and it is a marker of recent infection and this generally persists for 30-60days.IgG level also become elevated after 10-14 days and these become elevated throughout life. It shows late phase of disease or secondary infection. Virus isolation and HAI are considered the gold standard technique for virus and antibody detection respectively but they are rarely used since they are time consuming, costly and laborious.

Here we are tried to determine the accuracy of alternative diagnostic test i.e., Rapid immunochromatographic test that include NS_1 antigen, IgM & IgG antibody detection and comparing them with reference assay IgM capture ELISA provided by National Institute of Virology, Pune.

MATERIAL AND METHODS:

Present study was conducted in the Department of Microbiology, Patna Medical College, Patna with the help of medicine and other clinical department, during the period of September 2021 to October 2023**.** A total of 368 **c**linically diagnosed cases of dengue fever attending in OPD of our hospital were included in the study.

From all the patients 368 blood samples were collected and serum was separated. From all the serum tests were performed by rapid immunochromatographic test kit which can detect all three parameter NS_1Ag, IgM & IgG antibody according to packet insert by manufacturers guidelines. All the tests were compared by IgM capture Elisa[1].

The rapid immunochromatographic test take 20 minutes of time to give the result. Test kit contains two columns, one for NS_1antigen and other for detecting IgM & IgG antibodies[4,6,7]. In dengue NS_1antigen device if antigen is present in the sample it will bind to anti dengue NS_1gold colloidal conjugate making antigen- antibody complex. This complex migrates along the test region and form visible pink band.

IgM & IgG test line is coated with anti-human IgM and IgG. The appearance of pink band in a specific test region along with control line should be considered as positive for that particular antibody. All the sample was compared by IgM capture ELISA provided by NIV Pune as a reference standard. Positive OD value≥0.5and negative OD value<0.18 is considered. If OD value of sample exceeds OD of negative control by factor4.0 (sample OD≤ negative OD x4.0) the sample should be considered as positive.

RESULTS:

Out of 368 blood samples of dengue fever 136 samples were positive by rapid immunochromatographic test. Among 136 positive cases 127 cases were NS_1Ag positive, 05 cases are IgM reactive, 03 samples are IgG reactive and only 01 sample are reactive forNS_1, IgM & IgG. Out of 368 blood samples tested by dengue IgM capture Elisa only 123 cases (33.42%) were reactive. Most common age group affected by dengue fever was 21-30 years.
Table-1

Table -1: Shows distribution of Dengue fever blood samples positivity.

Total number of blood samples included in the study	Test result			
	Positive	Percentage	Negative	Percentage
368	136	36.95	232	63.05

Table -2: Shows distribution of positive rapid immunochromatographic test.

Rapid ICT	Total positive sample	Percentage
NS_1Ag	127	93.38
IgM	05	3.67
IgG.	03	2.20
NS_1, IgM & IgG.	01	0.75
Total	136	100%

Table -3: Shows comparative study of rapid ICT and IgM capture ELISA.

Total number of blood samples included in the study	Test result of ICT		Test result of IgM capture ELISA	
	Positive	Percentage	Positive	Percentage
368	136	36.95	123	33.42

DISCUSSION:

In our study it is found that most common age group affected by dengue fever was 21-30yrs.In 368dengue suspected 136 (36.95%) cases become positive by rapid ICT whereas 123 (33.42%) cases become positive by IgM capture ELISA. In rapid ICT 232 (63.05%) cases become negative where as in Elisa 245 (66.57%) cases become negative [6,7]. So, in comparison to ELISA, ICT is more sensitive however specificity is less than ELISA[1].

NS_1 is useful diagnostic marker in ICT. Compared with Elisa who takes four hours to completion of result but in case of rapid ICT takes only 20 minutes. Elisa cannot be performing with single or small number of samples. It is used for batch testing and urgent reporting is not possible in less number of samples and also costly with misuse of kit.

The rapid test does not involve any specific lab equipment it can be done at OPD set up, room temperature and only naked eye examination is required for interpretation of result. However as with other serological based assay it is essential to interpret the result with other relevant findings.

CONCLUSION:

If not intervened early stage of dengue can cause serious complication, rapid ICT is easy to perform even at primary health care level so that appropriate measure can be taken to reduce the morbidity and risk of mortality. Rapid ICT can be used in all health care system for speedy and accurate diagnosis and also for early notification of disease. It would ensure the initiation of control measure by public health authority.

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