Rapid Diagnostic Kits For Dengue - Are They Reliable??

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ABSTRACT:

objectives:

Rapid diagnostic test kits (RDT) for dengue have emerged as preferred diagnostic modality for quick diagnosis of dengue in india . though it has quickly gained acceptance as diagnostic modality for diagnosis for dengue but very few studies have been conducted so far to know its accuracy . This paper aims to evaluate the sensitivity and specificity of RDT for dengue in comparison to ELISA METHOD for diagnosis of dengue infection.

Design :A observational study of 100 suspected cases of dengue fever treated on outpatient or indoor basis was conducted from august 2018 to november 2019 in patna medical college and hospital . All suspected cases of dengue were tested for dengue antigen/antibody (IGM AND NS1 FOR DENGUE) , malaria (by peripheral blood smear for malarial parasite) , enteric fever (by IGM for enteric fever by ELISA and blood culture for salmonella typhi) urinary tract infection (by negative urine routine and culture) and chest X-ray . All cases who tested negative for malaria and enteric fever were tested for NS1/IGM for dengue by ELISA method and RAPID DIAGNOSTIC KIT. cases positive for NS1/IGM antibody for dengue by ELISA method were taken as confirmed cases of dengue fever. all these confirmed cases were tested by RAPID DIAGNOSTIC KIT for dengue . suspected cases testing positive by rapid diagnostic kits and negative by ELISA method were considered false positive cases . the results were analysed to obtain the diagnostic accuracy of RDT for diagnosis of dengue fever in comparison to ELISAmethod.

Results :

The analysis of results showed that SENSITIVITY , SPECIFICITY , POSITIVE PREDICTIVE VALUE AND NEGATIVE PREDICTIVE VALUE OF rapid diagnostic kit was 60 percent , 76 percent , 71 percent and 65.51 percent respectively in comparison to dengue antibody detection by ELISA method .

conclusion :

Rapid diagnostic tests have moderate sensitivity and specificity for diagnosis of dengue fever . Though useful for rapid diagnosis of dengue in resource poor and geographically isolated areas its not a reliable modality for diagnosis . Diagnosis based on NS1 AND / OR IGM antibody for dengue by ELISA method and POLYMERASE CHAIN REACTION are only reliable modalities for diagnosis of dengue fever.

KEYWORDS: RAPID DIAGNOSTIC KITS FOR DENGUE , ELISA FOR DENGUE.

I. INTRODUCTION:

Dengue viruses are arbovirus capable of infecting humans and causing disease.These infections may be asymptomatic or may lead to a) classical dengue fever(DF)or   b)   dengue hemorrhagic feverwithout shock(DHF) or c) dengue hemorrhagic fever with shock(DSS).

About 3.9 billion people in 128 countries are at risk of infection with dengue virus.the number of reported cases has increased from 2.2 million in 2010 to 3.2 million in 2015(**a**).In India the number of reported cases has increased from 99913 in 2015 to 157315 in 2019. in bihar the number of reported cases has increased from 1771 in 2015 to 6712 in 2019(**b**). it is found in urban and semi-urban areas and are now spreading to rural areas.

Rapid and accurate dengue diagnosis is of paramount importance for clinical management . various tests available to diagnose dengue fever and DHF are(**c**):

1) virus isolation from clinical samples like serum , plasma , washed buffy coat from patient , autopsy tissue from fatal cases (liver , spleen ,lymph node ,thymus) and mosquito collected from affected area.

2) virus nucleic acid(RNA) detection : by reverse transcriptase polymerase chain reaction(RT-PCR).

3) Immunological tests : hem-agglutination inhibition assay (HIA) , complement fixation test(CF) , neutralisation tests (NT) , IGM capture ELISA , indirect IGG ELISA and IGM/IGGratio.

4) Viral antigen detection : ELISA and dot blot assays directed against envelope membrane (EM) antigens and non structural protein 1

(NS1) can be detected in both patients with primary and secondary dengue infection upto 6 days after the onset of illness.

5) Rapid diagnostic tests (RDT) : a number of commercial rapid format serological test kits for anti-dengue IGM and IGG antibodies have become available in last few years and some of them produce results in 15 minutes . **unfortunately , the accuracy of most of these tests is uncertain since they have not been properlyvalidated.(d)**

of all commercially available methods determination of viral RNA by RT-PCR is the most sensitive and specific but due to cost consideration and limited availability it isnotwidelyused.detectionofNS1antigenandIGMantibodiesfordengueby

ELISA is commercially available and cost effective method of diagnosis as it is widely available . the current study aims to study the sensitivity and specificity of rapid diagnostic tests(RDT) for diagnosis of dengue fever in comparison to ELISA method.

II. METHOD:

100 OPD and and inpatients treated in patna medical college and hospital from august 2018 to nov 2019 who were suspected as case of dengue fever based on clinical presentation were tested for NS1 antigen and / or IGM antibody for dengue by ELISA method and RDT. NS1/IGM positive by ELISA were consider true positives while NS1/ IGM positivity by only RDT was considered false positives . the other common causes of fever like malaria , enteric fever , urinary tract infection and respiratory infection were ruled out based on clinical history and peripheral blood for malarial parasite , blood culture and IGM ELISA for enteric fever , urine culture and chest X-ray respectively .Detailed history for various symptoms was taken to study the frequency of various symptoms in these patients. the results were compared and diagnostic accuracy of RDT were calculated as per formulae.

OUTCOME:

	NS1/IGM POSITIVE BY ELISA METHOD (TRUE POSITIVES)	NS1/IGM NEGATIVE BY ELISA METHOD(TRUE NEGATIVES)
NS1/IGM POSITIVE BY RAPID DIAGNOSTIC KIT METHOD	30	12
NS1/IGM NEGATIVE BY RAPID DIAGNOSTIC KIT METHOD	20	38

III. RESULTS:

1)it was also found that proper clinical history(acute onset febrile illness with high grade continuous fever with moderate to severe body-ache and retro- orbital pain) and residence in areas of outbreak were strongly correlated with positive tests by ELISA method. of 50 serologically confirmed cases of dengue 46 percent patient had high grade fever , 38 cases had moderate to severe myalgia and body-ache and 16 had retro-orbital pain. 47 patients belonged to areas where outbreak of dengue had been reported thus proving the clustering ofcas

2)es.

2)Statistical formulae were used to derive diagnostic accuracy of rapid diagnostic kits(RDT)

for diagnosis of dengue taking ELISA method as reference . the sensitivity of RDT was found to be 60% while its specificity was found to be 76%. the positive predictive value of RDT was 71% while the negative predictive value was65.51%.

IV. REVIEW OF LITERATURE AND DISCUSSION:

Rapid diagnostic tests for diagnosis for dengue have only moderate sensitivity(60%) and positive predictive value(71%) for diagnosis of dengue fever while they have relatively higher specificity (76%). very few studies has been conducted in the past to assess the diagnostic accuracy of RDT for dengue .**study conducted by department of microbiology GSVM kanpur on**

80 patients using various kits available in the market had found the sensitivity of RDT for dengue ranging from 27.8% to77.7%(dependingon the type of kits) and specificity to be 50% to 86.2%. results of the current study have found similarresults.(e)

the results of the study highlight the fact that proper clinical history and residence in areas of outbreaks are equally important for making rapid clinical diagnosis of dengue fever and RDT are not suitable to make diagnosis of dengue . therefore only proper clinical history combined with serological detection of IGM/NS1 for dengue by ELISA method is only recommended method for diagnosis of dengue fever . it is also important to rule our common causes of fever like malaria , entericfever

, urinary tract infection and respiratory tract infection by clinical history and appropriate radiological and serological tests.

REFERENCES:
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