Comparative Analysis of Rapid Dengue Test v/s ELISA in Dengue fever admitted in KIMS hospital, Bengaluru.

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ABSTRACT

Background

Dengue fever is a benign syndrome caused by an arthropod-borne virus and is characterized by Biphasic fever, myalgia, and arthralgia, rash, leucopenia. Dengue hemorrhagic fever and dengue shock syndrome are a severe, often fatal febrile disease caused by 1 of 4 dengue virus. It is characterized by increased capillary permeability, abnormalities of hemostasis and protein-losing shock syndrome.
Dengue cases in India are increasing in epidemic proportions. The diagnosis of acute dengue infection is made by viral isolation and identification, viral nucleic acid detection, and serological tests for NS1 Antigen or IgM or IgG sero-conversion. The aim of this study was to compare rapid dengue test v/s ELISA test in dengue fever.

Methods

The present study is a comparative study between rapid dengue study and ELISA for detection of dengue fever , patients who are admitted in pediatric department included in study.Total 100 case were taken were enrolled in a structured protocol which included symptoms,sign,complication,Investigation.The diagnosis of dengue fever based on WHO criteria. All this data was recorded and entered in the predesigned semi structured questionnaires. The dengue rapid and ELISA reports were noted and the results were analyzed by Chi-square/ Fisher Exact test

Results

*In my study When the rapid ICT test for NS1 Ag was compared with the NS1 Antigen capture ELISA it showed P<0.001**, Significant ,it showed a sensitivity of 76.27 % specificity of 58.54 % and rapid test for IgM was compared with IgM ELISA sensitivity of 54.55 % specificity of 92.85 % P<0.001**, Significant and for IgG rapid test compared with ELISA sensitivity of 70.11 % specificity of 86.78 % P=0.014*, statistically Significant,*

Conclusion

Dengue fever is a self-limiting viral infection , accurate diagnosing and managing is very important , in our study showed rapid dengue test showed false negative for some dengue fever cases where ELISA was positive, so ELISA is better than dengue spot test and its very crucial to diagnose accurately and manage cases.

Keyword : - *dengue ELISA,Rapid test,Ns1,IgM,IgG,*

METHODS

This study was retrospective study conducted in Department of Pediatrics at Kempegowda Institute Of Medical Sciences Hospital, Bengaluru .Study was conducted for a period of 3 months from October 2019 to December 2019.

INTRODUCTION

Dengue fever is a systemic disease caused by single-stranded RNA-virus of the genus flavivirus and transmitted to human through the bite of infected Aedes mosquito, principally Aedesaegypti[1]. Dengue hemorrhagic fever and dengue shock syndrome are a severe, often fatal febrile disease caused by I of IV dengue virus.As per Indian data DEN-2 is the predominant circulating strain[2] Dengue virus serotype 2 (DEN-2) is known to cause high morbidity and mortality in Southeast Asia [3]While most patients recover following a self-limiting non-severe clinical course, small proportion progress to severe disease characterized by plasma leakage with or without hemorrhage.

Efficient and accurate diagnosis of dengue is of primary importance for clinical care i.e. for early detection of severe cases, case confirmation and to rule out other differential diagnosis. It is also important for the disease surveillance and outbreak control. The World Health Organization (WHO) guidelines identified three diagnostic tests as golden standards for dengue diagnosis: viral isolation and identification, by PCR [4] viral nucleic acid detection, and serological tests for IgM seroconversion.
Non-structural protein 1 (NS1) is a glycoprotein that is abundantly produced by DENV in the early stage of infection, and can be detected in the serum or plasma of the patients [5](Shan *et al*., 2015). After the onset of illness, the NS 1 antigen of virus can be detected in serum or plasma 4–5 days. After 05 days i.e. at the end of the initial phase of infection, IgM or IgG detection is the choice for diagnosis. As per case definition of dengue according to Indian national guidelines, a patient is labeled as a "probable case" if he satisfies the clinical criteria during dengue outbreak or positive non ELISA based immuno-chromatography tests (rapid test) such as NS1 antigen(Ag) / IgM ("National Guidelines for Clinical Management of Dengue Fever, Dec 2014.")[6]. A case is labeled as "confirmed" when NS1 Ag / IgM is positive by ELISA or demonstration of fourfold rise of IgG titer or detection of viral nucleic acids PCR or by culture and isolation of Dengue virus.

Materials and Methods

The present study is a comparative study between rapid dengue study and ELISA for detection of dengue fever , patients who are admitted in pediatric department included from 1 month to 18year who are all came with fever with dengue spot positive , exclusion criteria was dengue case with mixed infection .Total 100 case were taken were enrolled in a structured protocol which included signs and symptoms of dengue fever like fever ,pain abdomen ,vomiting ,loosestool, cough, complication, Investigation. The diagnosis of dengue fever based on WHO criteria i.e dengue fever without warning sign and dengue fever with warning sign and severe dengue . All this data was recorded . The dengue rapid and ELISA reports were noted and the results were analyzed by Chi-square/ Fisher Exact test.[7,8,9].

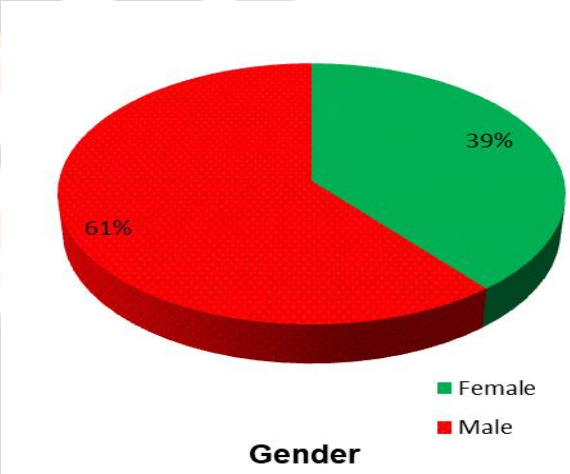
RESULTS and DISCUSSION

During the study period of 3months 100 cases dengue cases were admitted , among which 61 male and 39 were female, based on symptoms fever were most common symptoms , 96 cases fever , remaining 4 children's were afebrile on admission, The mean duration of fever on admission was 3 day. The mean duration of fever on admission was 3 day. The other common complaints were painabdomen 42 cases vomiting 55 cases, cough 26 cases, loose stool 26 cases and skin rashes 16 cases , bleeding manifestation included petechiae, Epistaxis , malena were 15 cases. Out of 100 cases dengue fever without warning sign 56 and dengue fever with warning sign 29 cases , and severe dengue 18 cases , all sever dengue cases admitted to PICU. Pleural effusion was documented in 7% of cases on chest x ray and 6% of cases, respectively. Hepatosplenomegaly in 4% of total children's. All the patients were managed with careful monitoring of blood pressure ,hematocrit , platelet counts on as and when required basis. All the patients were managed with careful monitoring of blood pressure , hematocrit, platelet counts on as and when required basis Fifteen children were severe dengue, of which 17 children had dengue circulatory shock, and 1 had major severe bleeding. Two children's on inotropes ,total 22 patients were transfused platelets out of which two cases were transfused SDP(single donor platelet), one patient transfused PRBC. Thrombocytopenia (Platelet count less than 1,00,000) was observed in 86 children . In most of the children, thrombocytopenia was observed between 3rd day to 6th day of fever. At the time of admission the platelet count was between 50,000-1,00,000 in 54 children, between 20,000-50,000 in 26 children and less than 20,000 in 6 children. And 12 cases of PEM out of which 7 cases were grade 2 and remaining are grade 3, one case presented as severe dengue.

When the rapid ICT test for NS1 Ag was compared with the NS1 Antigen capture ELISA it showed P<0.001**, Significant, spot test shoed 17 cases false negative. fig1,it showed a sensitivity of 76.27 % specificity of 58.54 % and rapid test for IgM was compared with IgM ELISA sensitivity of 54.55 % specificity of 92.85 % P<0.001**, Significant, fig2 and for IgG rapid test compared with ELISA sensitivity of 70.11 % specificity of 86.78 % P=0.014*, Significant, fig3.

In our study, there were 100 children with dengue serology positivity. Among the age and sex ratio, the majority of children were in the older age group more than six years and male to female ratio of 1.5:1. Among the symptoms, fever was the most commonly observed in 96% of children. Tamilselvam et al. In a similar study have quoted fever as the most common symptoms in more the 90%.[10] The other common symptoms were pain abdomen and vomiting. Similar study done , Hunsperger et al compared RDTs vs ELISA, study showed that NS1 ELISA sensitivity was 60-75% and specificity 71-80%; NS1 RDT sensitivity was 38-71% and specificity 76-80%; the IgM anti-DENV RDTs sensitivity was 30-96%, with a specificity of 86-92% [11] , Our study showed ELISA is better than dengue rapid test in diagnosing dengue fever. There was no significant difference in the symptoms and signs between the two groups. This study stresses on improving sensitivity and specificity of rapid diagnostic tests and to diagnose accurately and manage. However To make ELISA cost effective a large number of samples need to be processed at one go. To perform ELISA test, lab needs to be equipped with instruments like ELISA washer and reader.

Symptoms	Number of childrens
fever	96
Pain abdomen	42
Vomiting	55
Cough	26
Loose stool	26
Rashes	16
Bleeding manifestation	15



Dengue Serology NS1Ag vsDengue serology (ELISA)

Dengue Serology (RAPID): NS1Ag	**Dengue serology (ELISA): NS1Ag**		**Total**
	Negative	**Positive**	
Negative	24(58.5%)	14(23.7%)	38(38%)
Positive	17(41.5%)	45(76.3%)	62(62%)
Total	41(100%)	59(100%)	100(100%)

Fig1. P<0.001**, Significant, Chi-square test

Dengue Serology (RAPID): IgM vs Dengue serology (ELISA)

Dengue Serology (RAPID): IgM	Dengue serology (ELISA): IgM		Total
	Negative	Positive	
Negative	52(92.9%)	20(45.5%)	72(72%)
Positive	4(7.1%)	24(54.5%)	28(28%)
Total	56(100%)	44(100%)	100(100%)

Fig2. P<0.001**, Significant, Chi-square test

Dengue Serology (RAPID): IgG vsDengue serology (ELISA)

Dengue Serology (RAPID): IgG	Dengue serology (ELISA): IgG		Total
	Negative	Positive	
Negative	59(86.8%)	21(65.6%)	80(80%)
Positive	9(13.2%)	11(34.4%)	20(20%)
Total	68(100%)	32(100%)	100(100%)

Fig.3 P=0.014*, Significant, Chi-square test

Significant figures
+suggest significance (p value : 0.05<P<0.10)
* moderately siginificant(p value : 0.01< P≤0.05)
** strongly siginificant (p value : ≤P0.01)

4. CONCLUSIONS

Dengue fever is a self-limiting viral infection , accurate diagnosing and managing is very important , in our study showed rapid dengue test showed false negative for some dengue fever cases where ELISA was positive,so ELISA is better than dengue spot test and its very crucial to diagnose accurately and manage cases

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