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Microbiology

Comparative Evaluation of Dengue ICT with Immunocapture Elisa in a tertiary care hospital .

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ABSTRACT

Introduction: Dengue is considered as one of the world's major emerging tropical diseases. Dengue is the second most common tropical disease next to Malaria. Specific IgM and IgG detection has been the mainstay of diagnosis for a long time.

Aim and objectives: Comparative evaluation of ICT with Immunocapture ELISA in diagnosis of Dengue .

Materials and methods: Blood was drawn from 350 suspected dengue cases and were subjected to both ICT and ELISA.

Results: Out of 350 samples tested 107 were positive by ELISA (30.5%) and 92 by ICT (26.2%). Sensitivity, specificity, PPV and NPV of the ICT were calculated using MAC ELISA as reference.

Conclusion: Immunocapture ELISA is more sensitive and reliable than ICT even though it is highly specific, rapid and easy to perform.

KEYWORDS : Immunochromatographic test (ICT), MAC ELISA- IgM capture Enzyme linked immunosorbent assay,IgM-Immunoglobulin M, IgG—immunoglobulin G, NS1- non-structural1 protein.

INTRODUCTION

Dengue virus is increasingly recognized as one of the world's major emerging infectious tropical diseases[1].According to WHO, Dengue fever or Dengue haemorrhagic fever is considered as the **second most important tropical disease next to malaria[2].**

Dengue virus is a single stranded RNA virus with four serotypes. Infection with one serotype of Dengue does not confer cross protection against the other serotype. On subsequent infection it may lead to serious forms of disease like Dengue haemorrhagic fever and Dengue shock syndrome through immuno–pathological enhancement[3].

Clinically Dengue infection causes a wide spectrum of illness ranging from undifferentiated dengue fever, Dengue haemorrhagic fever and Dengue shock syndrome which can finally lead to death[3].

Commonly used diagnostic methods for Dengue are viral isolation, RT-PCR and serological methods. Viral isolation is a time consuming and fastidious process . RT-PCR even though detects the virus in early stage these methods remain expensive and technically difficult particularly in laboratory settings of the developing world[4].

Serological diagnosis of Dengue has many advantages like more flexibility, wide availability of reagents, low cost and requirement of less equipments3. One of the definite methods to diagnose early Dengue infection is to detect specific antigen which directly correlate with underlying viremia and pathogenesis of infection[4].

In view of the increased occurrence of Dengue and its complications, the study is undertaken to comparatively evaluate the performance of MAC ELISA and rapid card in the detection of dengue antigen and antibody.

Aim & Objectives: To compare and evaluate the efficacy of rapid card with Immunocapture Elisa in the diagnosis of dengue infection.

Materials and Methods: Prospective study over a period of 1 year from September 2011 to August 2012 carried out in the department of Microbiology.

Blood Sample of 5ml was drawn under aseptic precautions from 350 Dengue suspected patients after informed consent.serum was separated and subjected to ICT and Elisa following the kit instructions . Statistical analysis was done using SPSS version 17.

Results:

Table 1 Case detection by ICT and ELISA

Test	No. of Suspected Cases	No. of Positive Cases	Percentage
ICT	350	92	26.2%
ELISA	350	107	30.5%

Table 2 Detection of NS1, IgM, IgG by ICT and ELISA

Test	No of suspected cases	ICT	ELISA
NS1	350	36(10.2%)	50(14.2%)
IgM	350	62(17.7%)	73(20.8%)
IgG	350	54(15.4%)	65(18.2%)

Table 3 Cross tabulation of ICT and ELISA for Ns1

ICT	ELISA		Total
	Positive	Negative	
Positive	34	2	36
Negative	16	298	314
Total	50	300	350

Sensitivity 68%, Specificity 99.3%, PPV 94.4%, NPV 85.7%
Chi-square test =46.36, p value<0.001(significant)

Table 4 Cross tabulation of ICT and ELISA for IgM

ICT	ELISA		Total
	Positive	Negative	
Positive	59	3	62
Negative	14	274	288
Total	73	277	350

Sensitivity 80.8%, Specificity 98.9%, PPV95.1%, NPV 95.1%
Chi-square test =5.1, p value<0.05(significant)

Table 5 Cross tabulation of ICT and ELISA for IgG

ICT	ELISA		Total
	Positive	Negative	
Positive	51	3	54
Negative	14	282	296
Total	65	285	350

Sensitivity 81.3%, Specificity 98.9%, PPV 94.1%, NPV 96.32%
Chi-square test=41.3, p value< 0.001(significant)

Discussion:

ICT's for the detection of NS1,IgM,IgG antibodies have been developed by a number of commercial companies and have found wide applications because of their ease of use and rapidity of results.In this study irrespective of fever duration all the serological markers like

NS1,IgM,IgG were detected more by immunocapture ELISA than ICT.

Overall case detection by ICT in this study was 26.2 %(92) whereas for MAC ELISA it is 30.5 %(table 1). ICT is found to be less sensitive than ELISA and it also gives false negative &false positive results due to cross reaction with other flaviviruses. Detection of serological markers like NS1,IgM,IgG by ICT and ELISA showed positivity of 36%(10.2%),62(17.7%),54(15.4%) and 50(14.2%), 73(20.8%), 65(18.2%) by ELISA(ref table 2) which was found to be significant with p value <.0001. In a study by **Kulkarni et al**[5] 2011 showed low sensitivity in ICT. **Masao et al**[6] in Japan said that due to low sensitivity ICT cannot be used for screening purposes. **Tabasum et al**[7] showed that ICT cannot be used as stand alone test for dengue diagnosis. **Vaishali et al 2015**[8] had showed that rapid card should always be used with ELISA to confirm dengue diagnosis.

As diagnostic assays are usually evaluated in terms of sensitivity and specificity it was calculated using 2x2 cross tabulation with reference.

For NS 1 antigen the sensitivity , specificity ,NPV& PPV were 68%,99.3%, 94.4% &85.7% for ICT against ELISA (table 3).using chi-square test p value of <0.001 was obtained and statistically significant. **Subhash C Arya et al**[9] 2011 ICT showed 80-90% detection rate during first week. **Vu Ty Han et al**[10]**,** Thailand NS1 LFRT was found to be 100% specific in 11°dengue. **Vaishali et al**[8] 2015 showed that NS1 rapid card when combined with NS1 ELISA showed higher sensitivity.For IgM antibody it was 80.8%, 98.9%, 95.1%& 95.1%.(table 4) pvalue <0.05 & significant. In a study by Moorthy et al 11 2009 showed that accuracy indices for IgM in ICT were 81.85,75%,61% &89.6% and concluded that ICT cannot be used as stand alone test. For IgG 81.3%, 98.9%, 94.1%& 96.32%(table 5)p value of <0.001 found to be statistically significant.**M Moorthy et al** [11]**2009** showed the accuracy indices for ICT for IgG were low and concluded that ICT not to be used as stand alone test.

Muhammad **Zahoor et al** [12] concluded that Immunocapture ELISA is highly sensitive for dengue than Rapid card even though they are specific.

Conclusion: As per the results of this study ELISA is highly sensitive and preferable for diagnostic purposes compared to ICT and the use of Immunocapture ELISA in the test panel for dengue will reduce the false negativity thereby reducing the mortality and morbidity rate. Considering the moderate performance of ICT in this study the device cannot be used as stand alone test and it should be always supplemented by ELISA for the dengue diagnosis.

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