Enzyme Linked Immunosorbent Assay And Immunochromatography In The Evaluation Of Anti- Rubella Antibodies

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Citation

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Abstract

A new commercially available rapid screening immunochromatographic test (ICT) for Detection of anti-rubella IgG & IgM antibodies was compared with ELISA. Materials and methods: 161 serum samples were tested by immunochromatography card test (Rubella IgG/IgM, SD –Bioline) and were compared with a standard IgG & IgM ELISA (Ani Biotech Oy, Orgenium Laboratories, Vantaa, Finland). Results: ELISA and ICT showed a sensitivity and specificity of 63.4% and specificity of 77% and 36.6% and 22.52% respectively in detection of anti-rubella IgG antibodies .All samples were negative for IgM by both methods. Statistical analysis done using Chi- square test showed a significant difference in sensitivity and specificity between the two tests ($p< 0.05$). Conclusion: ELISA was superior in achieving a comparatively high sensitivity and specificity. The rapid test required little technical expertise, lesser time and could be done without elaborate equipment unlike the ELISA. If the low sensitivity and specificity of ICT could be corrected in the kit by using better high inbuilt sensitivity & specificity controls for anti-rubella IgG, then it could replace IgG ELISA in screening for rubella antibodies in peripheral laboratories.

INTRODUCTION

Rubella is a mild disease which ordinarily is benign in children and adults. However, if acquired during the first trimester of pregnancy it can damage the developing foetus. For this reason, serological testing to determine the immune status of women of child bearing age is important[1]. Non-immune pregnant women are at risk of contracting the infection from patients and unimmunized men[2].The detection of IgG antibodies is the only laboratory tool available to assess immune status to rubella virus.

Serological testing is universally used today to determine immune status and acute rubella infection[3]. ELISA test for rubella is objective, sensitive, specific, and economical. Seroprevalence studies conducted in support of rubella control activities typically use the quantitative detection by EIA of IgG in a single serum sample[4].

Recently more rapid, less complicated assays for rubella testing have been developed including Immunochromatography. Terada K et al have used Immunochromatography as a new rapid tool for rubella detection with fairly good success[5]. There is no data available in India regarding the use of ICT rapid kits in Rubella antibody detection. Primary interest of this study was to compare detection of IgG & IgM antibodies by these two techniques. This report is our comparative evaluation of Immunochromatography versus ELISA based on sensitivity and specificity.

MATERIALS AND METHODS

This study was undertaken in August 2010 after approval by the Institute Ethical committee. 161 purposive serum samples were collected from volunteers of our institute after taking written informed consent. Subjects suspected of having current infection with rubella virus were excluded. A 5ml blood specimen was obtained from each subject. The separated serum was stored at 4-8 C at the study site. Rubella specific IgG and IgM antibodies were detected by colloidal gold solid-phase Immunochromatography(Rubella IgG and IgM, SD-Bioline) and a commercial IgG enzyme linked immunosorbent assay (ELISA) Rubella IgG & IgM Kit (Ani Biotech Oy, Orgenium Laboratories, Vantaa, Finland) in accordance with manufacturer's instructions. Statistical analysis was done by Chi-square test.

RESULTS

A total of 161 samples were tested by both methods as

shown in Table 1. 130(80.75%) were positive by IgG ELISA, (6 samples showing uncertain results were excluded). 75 (46.58%) were positive by IgG ICT. All samples were negative for IgM antibodies by both techniques.

Table 2 shows the comparison of specificity and sensitivity between the two test procedures. ELISA showed a sensitivity of 63.4% and specificity of 77%. ICT showed a sensitivity of 36.6% and specificity of 22.52%. ELISA showed a high sensitivity and specificity when compared to ICT.

The difference in sensitivity and specificity between the two tests was found to be significant ($p < 0.05$) by Chi-square test.

Figure 1

Table 1 Reactive patterns of IgG ELISA vs. IgG ICT

Tests	No. of samples positive	Percentage positivity	Equivocal
ELISA	130	80.75	6
Immunochromatography	75	46.58	-

Figure 2

Table 2 Sensitivity and specificity of ELISA vs. ICT in detecting IgG antibodies

Criteria	ELISA	Immunochromatography
Sensitivity (%)	63.4	36.6
Specificity (%)	77.5	22.52

DISCUSSION

The aim of all rubella antibody detection techniques is to get maximum sensitivity with minimum sacrifice of specificity. When large volumes of samples are to be tested, a technique that is simple and fast to perform giving results that are reliable, easily interpreted and cost effective is required[1].

In our study IgG rubella ELISA showed 63.4% sensitivity and 77% specificity, this is comparable to Wittenburg et al who have shown 61.7% sensitivity & 95% specificity in their study[1]. In a study by Field et al, who evaluated 3 rubella ELISA kits, showed the following results/RUBELISA showed a sensitivity of 95.6% & a specificity of 97%, Enzygost-Rubella 99.26% , 100% and Ortho rubella 100% & 97.32% respectively[6].

In a study similar to ours, Terada K et al have compared ICT assay with ELISA for detection of IgG antibodies against rubella. ELISA showed 100% sensitivity & specificity, and ICT showed 99.35% and 100%[5].Wu Jian Mei et al have used An IgM ICT in detecting IgM antibodies to TORCH. They found 100% sensitivity and specificity with ICT[7]. In an epidemiological investigation of rubella by Mu Ying et al, they observed that IgG ICT was a highly sensitive and specific test[8]. The low sensitivity (36.6%) & specificity (22.5%) of ICT in our study was probably due to poor controls in the kit.

CONCLUSION

ELISA continues to be the gold standard for detection of immunity against rubella. Though it is highly sensitive and specific, it is cumbersome to perform, requires trained technical personnel and reports have long turnaround time. On the other hand, ICT assay is a rapid test has been added to the battery of available rubella tests. This test unlike ELISA requires no pre -treatment of sera, elaborate equipment and can be performed in a matter of minutes. If ICT had high inbuilt sensitivity and specificity controls, as shown by other authors, it could be an acceptable alternative to ELISA. ICT could very well be most useful for clinical laboratories performing tests for where immediate results are required for management of patients.

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