INTRODUCTION

Beta-haemolytic *Streptococcus pyogenes* is major cause of upper respiratory infections such as pharyngitis, tonsillitis and scarlet fever. The symptoms and severity of the complications can be reduced by timely diagnosis and appropriate antibiotic treatment (Facklam and Carey 1985). Traditional diagnosis has been performed by cultivation of throat swab sample. The performance of a novel, quantitative Group A Streptococcus (GAS) rapid antigen detection test (RADT), ReaScan™ Strep A antigen test (RSGASADT) was evaluated in comparison to plate culture. The unique setting of one nylon swab sample per patient was applied. The quantitation of Strep A colonies and detection limit of ReaScan™ Strep A test were optimized.

METHODS

RSGASADT is a modified immuno-chromatographic lateral-flow test for the detection of Lancefield group A antigen present in GAS. In the test, GAS antigen is extracted from the throat swab with Extraction Reagents 1, 2 and 3. The extract is then allowed to react with GAS specific antibodies conjugated to gold particles in the test tube. Strep A antigen-antibody complexes are formed. After pipetting to the test membrane, this mixture migrates in it and membrane-bound GAS antibodies capture the gold particle - GAS antigen complex causing appearance of a red test line. The intensity of the test line is read by ReaScan™ reader which gives a numerical value respective to the concentration of the antigen in the sample. The study material consisted of throat swab samples of 113 consecutive patients with suspect GAS pharyngitis. The questionnaire for McIsaac-scoring was performed to each patient before sampling. Sampling was done with flocked nylon swabs which were immediately immersed in liquid Amies solution (eSwab, microRheologics, Brescia, Italy) and transported to the laboratory. In the laboratory, the sample tubes were vortexed and the swab was discarded. 100 µl aliquots of the homogenate and of its three water dilution (1/10, 1/100, and 1/1000) were subjected for both plate culture and RSGASADT.

RESULTS

GAS grew in 34/112 samples. The RSGASADT readings of the culture-positive samples were from 8 to 431, 0 – 70 of the samples with no beta-haemolytic growth, and 0 – 129 of samples with beta-haemolytic growth other than GAS. Applying a cut-off value of 25, altogether 28/34 culture-positive samples were positive by the RSGASADT and 10 false positives were detected. The sensitivity of RSGASADT was assessed by comparing the ReaScan readings and the corresponding plate counts (cfu’s) and it was found statistically significant (p=0.0005). Based on these results and the using the cut-off value of 20, the sensitivity of RSGASADT is 4 x 10⁴ cfu/ml (95% CI: 3 – 9 x 10⁴ cfu/ml) Both culture and rapid direct antigen detection were done using the same, homogenized sample. In the study of Giggs (ASM 2007, Abstr. # C-365) eSwab retained well both the viability and the Lancefield group antigen of GAS. Based on this information, culture and antigen detection results in our study are as comparable as they can be. By using the same sample for both analyses, the problems arising from the use of separate swab samples for culture and for antigen detection are avoided. The ReaScan™ Strep A test appears both sensitive and specific.

CONCLUSIONS

The study was performed for assessing the cut-off value and sensitivity of ReaScan GAS rapid antigen detection test. Based on discrepancy analysis, we ended up to a cut-off value of 20. Using this cut-off value, the specificity and sensitivity of RSGASADT were 82.4% and 87.2%. A strong correlation between the bacterial concentration of the sample and ReaScan reading was found around the cut-off area and the cut-off 20 was found to correspond bacterial density of 4 x 10⁴ cfu/ml of the sample. The ReaScan™ Strep A is suitable for point-of-care testing of GAS with minimum training, and its performance is comparable to standard laboratory methods for GAS.