Evaluation of a new test for the diagnosis of Amebiasis

Amebiasis is a parasitic infection caused by *Entamoeba histolytica* and one of the most common parasitic infections world-wide, infecting about 50 million people and resulting in 10,000 to 40,000 deaths per annum.

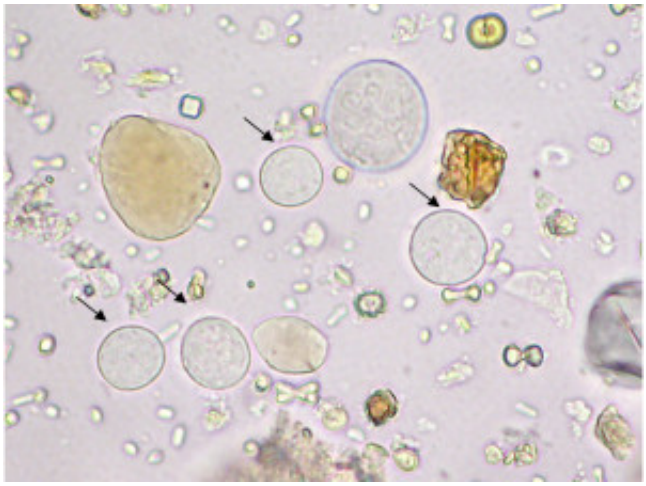

Fig. 1. Cysts compatible with *E. histolytica/ E. dispar/ E.moshkovskii*. (400x)

The diagnosis of *E. histolytica* infection has traditionally relied upon microscopic examination of fresh or fixed stool specimens. However, microscopy has several limitations; the most important is the inability to distinguish the pathogenic species *E. histolytica* from the morphologically identical non-pathogenic species *E. dispar* and *E. moshkovskii*. (Fig. 1)

Recently, molecular analysis like real-time PCR assay has been reported to show excellent sensitivity and specificity and it has been approved by the World Health Organization as the current method of choice for the diagnosis of *Entamoeba histolytica* infection. Unfortunately real-time PCR methods are not routinely available in most laboratories, especially in low-middle income countries. A rapid fecal antigen detection test could be a valid, alternative method for the diagnosis of *E. histolytica* in resource-limited settings.

Using our in home real-time PCR as gold standard, we evaluated a new antigen *E. histolytica* detection test, based on immunochromatographic technology. ImmunoCard STAT ® CGE, is a new test which uses specific monoclonal antibodies against *Cryptosporidium parvum*, *Giardia lamblia* and *Entamoeba histolytica* that detects all forms of the parasites during their life cycle.

To evaluate the test one-hundred fourteen samples were tested with the new rapid diagnostic test.

Of the 106 stool specimens tested, 18 were positive for E. *histolytica* by real-time PCR, of which 16 were positive by ImmunoCard STAT, indicating a sensitivity of 88%. Of the 49 negative stool samples at the real-time PCR, 46 were confirmed by the ImmunoCard STAT assay (specificity 93.8% if assessed on this denominator). Of 39 samples positive for E. *dispar* at real-time PCR, 31 (79%) resulted positive at the Immunocard STAT assay. (Tab. 1).

real-time PCR		ImmunoCard STAT	
		Positive	Negative
E. histolytica (18)		16	2
E. dispar (39)		31	8
Negative (49)		3	46
Tot.	106	50	56

Tab. 1. Comparison of results of real-time PCR and ImmunoCardSTAT assay performed on stool specimens.

Of 8 specimens obtained from drainage of liver abscess, 7 were positive for *E. histolytica* by real-time PCR, of which 2 (28%) were positive by Immunocard STAT.

The results of our study showed a reasonable sensitivity of the new test (88%). Specificity was also good (93.8%) if assessed over the denominator of negative samples at real-time PCR, but the test was not able to distinguish the species within the *Entamoeba* complex in stool samples, probably detecting a common antigen of *E. histolytica*/*E. dispar* rather than a specific Ag for the former. Concerning liver abscess, the performance of ImmunoCard STAT was not good; only 2 out of 7 (28%) positive real-time PCR samples were detected by the antigen test.

In conclusion, our results suggest that ImmunoCard STAT may be considered a good test for *Entamoeba* complex as a whole, but not for species identification, that should best rely on real-time PCR in order to correctly diagnose patients, reducing the morbidity and mortality of amoebiasis and minimizing unnecessary treatments of infections with non-pathogenic species.

Publication

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