

*Neurology* 2011; 76 (Suppl. 4): A66.

## **A Meta-Analysis on the Performance of the gMS-Classifer Dx Blood Test for Differentiating RRMS Patients from Other Neurological Disease Patients**

J Yarden<sup>1</sup>, A Dukler<sup>1</sup>

<sup>1</sup>Glycominds, Modi'in, Israel

**Objective:** A meta-analysis on 1278 patients, for summarizing the overall diagnostic performance of the gMS-Classifer Dx blood test for differentiating relapsing remitting multiple sclerosis (RRMS) from other neurological disease (OND) patients.

**Background:** RRMS patients have high serum levels of IgM antibodies against the  $\alpha$ -glucose based antigen GAGA4. The gMS-Classifer-Dx biomarker was created by normalizing anti-GAGA4 levels for total serum IgM levels, which minimizes the affect of immunosenescence and gender differences in IgM levels.

**Design/Methods:** We selected cohorts including both RRMS or first MS presentation patients, and OND patients that were screened by the gMS-Classifer-Dx blood test (n=1278). The meta-analysis included data from five cohort studies published before October 2010. In total there were 912 RRMS patients and 366 OND patients (149 other demyelinating diseases, 48 other inflammatory neurological diseases, 139 other non-inflammatory neurological diseases and 30 patients with positive neurological antigen). The diagnostic performance of gMS-Classifer Dx was tested by fixed and random effects analyses, calculating diagnostic-odds ratio (dOR) and 95% confidence intervals (CI). Heterogeneity among studies was measured by the Q statistic.

**Results:** A higher proportion of RRMS patients (297/912, corresponding to sensitivity 33%) were positive for the gMS-Classifer-Dx test compared to MS differential diagnosis patients (34/366, corresponding to specificity 91%) and was found to be similar in all five cohorts (Q-test for heterogeneity, p=0.24). The overall, dOR of the gMS-Classifer-Dx test according to fixed-effects model was 5.4, 95% CI, 3.5-8.3, p-value<0.05.

**Conclusions:** gMS-Classifer-Dx test is a highly specific "rule in" test for the differential diagnosis of RRMS.

Such a rule in test has potential to be a complementary diagnostic tool for baseline MRI, which only has moderate sensitivity (~70%) and specificity (~70%) for diagnosing MS at first presentation. <sup>1,2</sup>

1. Dalton et al., *Ann Neurol* 2002; 52:47-53.

2. Tintore et al., *Neurology* 2003; 60: 27-30.