OA-007 MOLECULAR BACTERIAL LOAD ASSAY: A FAST AND ACCURATE MEANS FOR MONITORING TUBERCULOSIS TREATMENT RESPONSE

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Background Tuberculosis is a difficult disease to treat. We report a multi-centre performance evaluation of the molecular bacterial load assay (MBLA) that monitors change in patient bacterial load (BL) as they respond to TB therapy.

Methods Smear or Xpert MTB/RIF-positive patients were prospectively monitored for treatment response using MBLA and culture at four sites in Southeast Africa. Treatment response was defined as decline in BL and or rise in time to culture positivity (TTP) or conversion to negative culture status. Positive culture at 5 or 6 months confirmed treatment failure. MBLA-MGIT correlation and association with treatment outcome were determined by Spearman's ρ and logistic regression, respectively.

Results A total of 1764 serial samples from 178 patients were assessed for treatment response of which 91% were treatment success. Of those who failed treatment (n=17), MBLA detected TB in 82% at 2 months of treatment compared to MGIT 24% and LJ 6%. Mean BL at baseline was 6±1.3log10 CFU/ml falling to zero in 59% of the patients by 3 months of treatment. A corresponding rise in MGIT TTP, 5±3 to 22±11 was observed, r=–0.5, p<0.0001. The rate of sputum clearance (SLOPE) was high among high-burden patients – 1.0log10C-FU/ml than low-burden patients, –0.7log10CFU/ml in the first 2 weeks of treatment. Despite higher rates of clearance, high-burden patients were more likely to be TB-positive at 2 months of treatment, p=0.01(OR 2.5). Response was generally slower among the MDR than susceptible TB patients. Time to result was 4h with MBLA and 5–22 days for MGIT. Contamination was 25% in MGIT and 4% on solid culture.

Inter-site testing revealed that MBLA was reproducible, ANOVA p >0.05.

Conclusions MBLA is a contamination-insensitive, reproducible method capable of giving results in real-time. Direct quantification of bacterial load from uncultured sputum demonstrates considerable potential for application in resource-limited settings where TB culture facilities are scarce.