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Poster Session III

Recent advances in molecular diagnosis of *M. tuberculosis*

EVALUATION OF AN ARRAY-BASED TEST FOR THE DETECTION OF ISONIAZID AND RIFAMPICIN RESISTANCE IN MYCOBACTERIUM TUBERCULOSIS CLINICAL STRAINS AND SAMPLES

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Objectives: Drug resistant tuberculosis (TB) has become a global threat due to emergence and spreading of multidrug resistant (MDR) TB strains, which are resistant to the first-line drugs isoniazid (INH) and rifampicin (RIF). The objective of this study is to evaluate an array-based molecular method to detect resistance to INH and RIF in both clinical isolates and clinical samples.

Methods: Seventy clinical strains, isolated from 70 patients, and 50 clinical samples from 25 patients were retrospectively selected. The array method (GenoFlow DR-MTB Array Test Kit [DiagCor Bioscience, Hong Kong]) performed detects the presence of mutations associated to resistance to INH and RIF. The genotypic results obtained by the array test were compared to those obtained by BACTEC 460TB or MGIT960. Discordant results obtained by both methods were analyzed by alternative molecular methods (sequencing, GenoType MTBDR*plus* [Hain Lifescience, Alemania] and/or pyrosequencing).

Results: The global concordance rates between results of both GenoFlow DR-MTB Array and BACTEC 460TB/MGIT for detecting resistance to INH and RIF in clinical isolates were 74.3% (52/70) and 97.1% (68/70), respectively. The array results which were discordant with the phenotypic result were confirmed by all the alternative molecular methods in 77.8% of the cases for INH resistance. For the remaining discordant results, regarding both INH and RIF resistance detection, the result obtained by GenoFlow DR-MTB Array was confirmed by one of the alternative molecular methods but not with the others. The global concordance rates for detecting resistance to INH and RIF in clinical samples were 98.0% (48/49) and 93.9% (46/49), respectively. The array results which were discordant with the phenotypic result were confirmed by alternative molecular methods in the case of INH resistance but in any case for RIF resistance detection.

Conclusions: The array-based method GenoFlow DR-MTB is useful for the rapid identification of multidrug resistant TB in both clinical isolates and clinical samples, thus allowing a initial therapeutic approach. Nevertheless, for a correct management of drug resistant TB patients, the results should be confirmed by a phenotypic method.