E023

2-hour Educational Workshop

The impact of diagnostics on clinical tuberculosis management

PCR and direct amplification for TB

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Tuberculosis diagnosis relies on clinical and radiological signs and bacteriological findings showing that *Mycobacterium tuberculosis* complex is present in pulmonary (70 % of the cases) or extra-pulmonary specimens. PCR has been developed in the 1990's and its use is not well standardized yet, even in European countries, where recommendations vary depending on the country and the cost-efficiency of these assays. Many kits are commercially available.

The review of the studies reporting PCR performances and medical relevance need to examine again the definitions of sensitivity, specificity and predictive values. Because the sensitivity of PCR assays is still lower than that of culture (if the patient has not started treatment), it seems not useful to test systematically extra-respiratory specimens which are usually pauci-bacillary, except for some which are smear-positive. On the contrary, it seems cost-effective to test by PCR all the smear-positive specimens as discovered by the lab as new patients. Because specificity cannot reach 100% (because of lab organization or other reasons), microbiologists need to be very careful if they test systematically smear-negative specimens, even pulmonary ones, since in most European countries the prevalence of TB-positive specimen among all received in the lab, is less than 5%, and consequently the positive predictive value is under 50% (one positive out of two is a false-positive result). Moreover, it might be difficult to found it cost-effective, unless the PCR test is cheap or the patient is hospitalized for a long time waiting for the result. If the patient is TB –confirmed by the PCR test, it is useful to screen for multi-drug resistance, i.e. rifampicin and isoniazid resistance, also by molecular detection. Again, the PPV will vary depending on the MDR prevalence in the country where the patient comes from. Confirmation of MDR resistance by a second test and by phenotypic testing is clinically relevant before starting a MDR TB treatment regimen.