

## Peran metode TB-LAMP dalam mendeteksi mycobacterium tuberculosis dari sputum pasien terduga tuberkulosis paru = The Role of TB-LAMP method in detecting mycobacterium tuberculosis from sputum patients suspected of pulmonary tuberculosis

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### Abstrak

Insiden tuberkulosis (TB) di Indonesia merupakan salah satu yang tertinggi di dunia. Penegakan diagnosis secara tepat merupakan salah satu upaya untuk mengendalikan TB. Modalitas uji diagnostik laboratorium TB yang tersedia yaitu pemeriksaan mikroskopis Basil Tahan Asam (BTA) dan pemeriksaan biakan memiliki beberapa keterbatasan. Secara global, terjadi peningkatan dalam penggunaan Tes Cepat Molekuler (TCM) sebagai uji diagnostik laboratorium TB. Salah satu TCM yang telah direkomendasikan oleh World Health Organization (WHO) yaitu loop-mediated isothermal amplification (LAMP). Oleh karena itu, perlu dilakukan penelitian untuk mengevaluasi metode LAMP, sehingga metode tersebut dapat diterapkan secara rutin di Indonesia. Penelitian dilaksanakan di Laboratorium Mikrobiologi Klinik Fakultas Kedokteran Universitas Indonesia (LMK-FKUI) terhadap 100 orang pasien terduga TB paru. Setiap pasien menyerahkan dua sputum langsung, yaitu sputum sewaktu dan sputum pagi/sewaktu. Terhadap setiap sputum langsung kemudian dilakukan pemeriksaan mikroskopis BTA. Dua sediaan sputum langsung dari setiap pasien kemudian digabung untuk menghasilkan mixed sputum. Terhadap setiap mixed sputum dilakukan pemeriksaan mikroskopis BTA, biakan Lowenstein-Jensen (LJ) dan pemeriksaan TB-LAMP. Biakan yang tumbuh diidentifikasi menggunakan tes MPT64. Hasil penelitian menunjukkan nilai kappa (κ) pemeriksaan mikroskopis BTA antara sputum langsung dan mixed sputum sebesar 0,88;  $p < 0,001$  (95% CI 0,78-0,97). Persentase hasil LAMP (+) pada sputum langsung dengan hasil BTA (-) sebesar 28,07%, sedangkan persentase hasil LAMP (+) pada mixed sputum dengan hasil BTA (-) sebesar 32,78%. Metode TB-LAMP memiliki nilai sensitivitas sebesar 100% (95% CI 89,56-100%) dan spesifisitas sebesar 69,64% (95% CI 55,74-80,84%). Nilai duga positif TB-LAMP sebesar 71,19% (95% CI 57,73-81,86%), sedangkan nilai duga negatif TB-LAMP sebesar 100% (95% CI 88,83-100%). Pada hasil mikroskopis BTA yang sesuai (concordant) dengan biakan TB, nilai sensitivitas dan spesifisitas TB-LAMP berturut-turut sebesar 100% (95% CI 89,09-100%) dan 73,58% (95% CI 59,42-84,32). Adapun nilai sensitivitas TB-LAMP pada hasil mikroskopis BTA yang tidak sesuai (discordant) dengan biakan TB, yaitu sebesar 100% (95% CI 19,79-100%). Metode TB-LAMP memiliki nilai sensitivitas dan nilai duga negatif yang tinggi. Untuk menegakkan diagnosis TB paru secara tepat, metode TB-LAMP harus dikombinasikan dengan gejala dan tanda yang terdapat pada pasien.

.....The incidence of tuberculosis (TB) in Indonesia is one of the highest in the world. Appropriate diagnosis is an effort to control TB. Existing TB laboratory diagnostic test modalities, which are Acid-Fast Bacilli (AFB) smear and culture examination have several limitations. Globally, there has been an increase in the use of the molecular rapid test as a TB laboratory diagnostic test. One of the molecular rapid tests recommended by the World Health Organization (WHO) is loop-mediated isothermal amplification (LAMP). Therefore, research is needed to evaluate the LAMP method, so that the method can be applied routinely in Indonesia. The study was conducted at the Clinical Microbiology Laboratory of the Faculty of

Medicine, Universitas Indonesia for 100 patients suspected of pulmonary TB. Each patient handed over two direct sputums, which are the spot sputum and morning/spot sputum. Against each direct sputum, an AFB smear was carried out. Two direct sputum preparations from each patient were then combined to produce mixed sputum. For each mixed sputum, AFB smear, Lowenstein-Jensen (LJ) culture and TB-LAMP examination were carried out. Cultures that were grown were identified using MPT64 tests. The results of the study showed that the kappa ( $\kappa$ ) value of AFB smear between direct sputum and mixed sputum was 0.88;  $p < 0.001$  (95% CI 0.78-0.97). The percentage of LAMP (+) in direct sputum with AFB (-) was 28.07%, while the percentage of LAMP (+) in mixed sputum with AFB (-) was 32.78%. The TB-LAMP method had a sensitivity value of 100% (95% CI 89.56-100%) and a specificity of 69.64% (95% CI 55.74-80.84%). Positive predictive value of TB-LAMP was 71.19% (95% CI 57.73-81.86%), while the negative predictive value of TB-LAMP was 100% (95% CI 88.83-100%). In concordant AFB smear results with TB culture, the TB-LAMP sensitivity and specificity values were 100% (95% CI 89.09-100%) and 73.58% (95% CI 59.42-84.32), respectively. The sensitivity value of TB-LAMP on AFB smear results which were discordant with TB culture was 100% (95% CI 19.79-100%). The TB-LAMP method had a high sensitivity value and negative predictive value. To properly diagnose pulmonary TB, the TB-LAMP method must be combined with the symptoms and signs that the patient has.