Analisis Perbandingan Akurasi Dua Alat Uji Point Of Care Lipoarabinomannan Urin untuk Diagnosis Tuberkulosis Anak Tanpa HIV = Comparative Analysis of the Accuracy of Two Point-of-Care Testing (POCT) Urine Lipoarabinomannan for Tuberculosis Diagnosis in HIV Negative Children

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Abstrak

Latar belakang: Diagnosis tuberkulosis (TB) pada anak sulit ditegakkan karena gejala tidak khas dan sulit memperoleh sampel sputum. Pemeriksaan antigen lipoarabinomannan (LAM) urin telah direkomendasikan oleh WHO. Namun, penelitian pada anak tanpa HIV di Indonesia masih sangat terbatas. Mengingat kesulitan dalam mendapatkan sampel sputum pada anak tanpa HIV, diperlukan metode diagnostik non-sputum yang mudah dilakukan, memberikan hasil cepat, serta dapat diterapkan langsung di lokasi pasien (point-of-care testing atau POCT).

Tujuan: Menilai dan membandingkan akurasi diagnostik dua alat deteksi LAM urin yaitu Abbott Determine TB LAMAg TM (Abbott LAM) dan Fujifilm SILVAMP TB LAM TM (Fuji LAM) untuk mendiagnosis TB pada anak.
Metode: Penelitian ini merupakan studi potong lintang yang melibatkan anak berusia 0 - 18 tahun dengan dugaan TB di tiga rumah sakit rujukan nasional. Data dikumpulkan melalui anamnesis, pemeriksaan fisis, serta pengambilan sampel urin menggunakan metode midstream atau urine collector. Sampel urin kemudian diperiksa menggunakan Abbott LAM dan Fuji LAM, lalu dibandingkan dengan standar diagnosis TB menurut Pedoman Kemenkes RI 2023 (TB klinis dan TB terkonfirmasi bakteriologis) serta standar pemeriksaan bakteriologis (GeneXpert®).
Hasil: Pada periode Oktober hingga Desember 2024, sebanyak 77 pasien dianalisis, dengan 18 pasien terkonfirmasi bakteriologis dan 22 pasien didiagnosis TB secara klinis.
Dibandingkan dengan alur diagnosis Kemenkes RI 2023 sebagai standar: Abbott LAM memiliki sensitivitas 52% dan spesifisitas 48,6%, Fuji LAM memiliki sensitivitas 22,5% dan spesifisitas 97,3%. Dibandingkan dengan pemeriksaan bakteriologis sebagai standar: Sensitivitas dan spesifisitas Abbott LAM menurun menjadi 47,1% dan 42,5%, sensitivitas dan spesifisitas Fuji LAM meningkat menjadi 47% dan 97,5%.
Kesimpulan: Kedua alat memiliki sensitivitas yang lebih rendah dari standar minimal WHO (65%), sehingga tidak direkomendasikan untuk skrining atau diagnosis awal TB pada anak. Namun, Fuji LAM menunjukkan spesifisitas tinggi dan berpotensi menjadi alat diagnostik penguat dalam mendeteksi TB pada anak yang menunjukkan gejala, terutama bagi anak yang mengalami kesulitan dalam memperoleh sampel untuk pemeriksaan bakteriologis
.....Background: Diagnosing tuberculosis (TB) in children is challenging due to non-specific symptoms and difficulties in obtaining sputum samples. The World Health Organization (WHO) has recommended urinary lipoarabinomannan (LAM) antigen testing for TB detection. However, studies on HIV-negative children in

Indonesia remain very limited. Given the challenges in obtaining sputum samples from HIV-negative children, a non-sputum diagnostic method that is easy to perform, provides rapid results, and can be implemented at the point of care (POCT) is needed.
Objective: To evaluate and compare the diagnostic accuracy of two urinary LAM detection tests, Abbott Determine TB LAM Ag™ (Abbott LAM) and Fujifilm SILVAMP TB LAM™ (Fuji LAM), for diagnosing TB in children.
Methods: This cross-sectional study involved children aged 0–18 years with suspected TB from three national referral hospitals. Data collection included medical history, physical examination, and urine sample collection using either the midstream method or a urine collector. Urine samples were tested using Abbott LAM and Fuji LAM, and results were compared with the 2023 Indonesian Ministry of Health TB diagnostic guidelines (clinical TB and bacteriologically confirmed TB) as well as the bacteriological testing standard (GeneXpert®).
Results: Between October and December 2024, a total of 77 patients were analyzed, including 18 bacteriologically confirmed TB cases and 22 clinically diagnosed TB cases. When compared to the 2023 Indonesian Ministry of Health TB diagnostic algorithm, Abbott LAM showed a sensitivity of 52% and specificity of 48.6%, while Fuji LAM had a sensitivity of 22.5% and specificity of 97.3%. When using bacteriological testing (GeneXpert®) as the reference standard, the sensitivity and specificity of Abbott LAM decreased to 47.1% and 42.5%, respectively, whereas Fuji LAM demonstrated improved performance with a sensitivity of 47% and specificity of 97.5%.
Conclusion: Both tests demonstrated lower sensitivity than the WHO-recommended minimum standard (65%), making them unsuitable for screening or initial TB diagnosis in children. However, Fuji LAM exhibited high specificity, suggesting that it may serve as a valuable additional diagnostic tool for children with TB symptoms who face challenges in providing sputum samples for bacteriological confirmation.