Hubungan antara efek samping obat dengan luaran pengobatan pada pasien Tuberkulosis Resisten Obat (TB RO) di RSUP Persahabatan tahun 2021 - 2023 = The relationship between adverse drug reactions and treatment outcomes in patients with Drug-Resistant Tuberculosis (DR TB) at Persahabatan General Hospital from 2021 - 2023

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Abstrak

Latar belakang: Kompleksitas pengobatan TB RO berupa durasi pengobatan yang panjang, penggunaan beberapa obat lini kedua, toksisitas obat, dan interaksi obat akibat multidrug use dapat menyebabkan efek samping pengobatan pada pasien. Hal ini dapat mengurangi efektivitas pengobatan dan memengaruhi luaran pengobatan TB RO. Tujuan: Untuk melihat efek samping obat/kejadian tidak diinginkan terhadap luaran pengobatan TB RO.
Metode: Penelitian observasional dengan desain kohort retrospektif ini dilakukan di RSUP Persahabatan, Jakarta. Sumber data adalah data sekunder dari sistem informasi tuberkulosis (SITB) yang melibatkan pasien TB RO yang menjalani pengobatan di tahun 2021 – 2023. Metode sampling berupa total sampling. Analisis data bivariat antara KTD dengan luaran pengobatan TB RO berupa Cox regresi dan uji Log-Rank, yang kemudian dilanjutkan dengan analisis multivariat menggunakan Extended Cox Regresi.
Hasil: Dari 583 subjek yang diikutsertakan dalam penelitian ini, insidens luaran pengobatan tidak berhasil sebanyak 40,65%. Sebanyak 12,69% pasien mengalami efek samping berat. Sebagian besar efek samping terjadi pada fase intensif pengobatan TB RO (43,57%). Jenis efek samping yang paling sering dialami pada pasien adalah gangguan gastrointestinal (79,25%), gangguan muskuloskeletal (58,32%), dan gangguan saraf (49,40%). Efek samping berupa KTD berat/serius tidak memiliki asosiasi yang signifikan terhadap terjadinya pengobatan tidak berhasil berdasarkan hasil analisis Cox regresi bivariat (HR=0,823; 95% CI: 0,558-1,216; p=0,329) dan analisis multivariat Extended Cox regresi (setelah dikontrol oleh variabel kovariat). Probabilitas survival antara kelompok dengan KTD berat dan kelompok non-KTD berat tidak berbeda bermakna. Kesimpulan: pemantauan efek samping selama pengobatan TB RO berlangsung merupakan hal yang penting untuk menunjang keberhasilan pengobatan.
.....Background: The complexity of treating drug-resistant tuberculosis (DR TB) involves prolonged treatment duration, the use of several second-line drugs, drug toxicity, and drug interactions due to multidrug use, which can lead to adverse drug reactions in patients. These issues can reduce treatment effectiveness and affect treatment outcomes for DR TB.
Objective: To investigate the impact of adverse drug reactions/adverse events on DR TB treatment outcomes.
Methods: This observational study utilized a retrospective cohort design conducted at RSUP Persahabatan, Jakarta. The data source was secondary data from the tuberculosis information system (SITB) involving DR TB patients who underwent treatment between 2021 and 2023. The sampling method was total sampling. Bivariate data analysis between adverse events and TB RO treatment outcomes involved Cox regression and Log Rank tests, followed by multivariate analysis using Extended Cox Regression.
Results: Among the 583 subjects included in this study, the incidence of unsuccessful treatment outcomes

was 40.65%. Severe adverse drug reactions were experienced by 12.69% of patients. Most adverse reactions occurred during the intensive phase of TB RO treatment (43.57%). The most common types of adverse reactions experienced by patients were gastrointestinal disorders (79.25%), musculoskeletal disorders (58.32%), and neurological disorders (49.40%). Severe/serious adverse reactions did not have a significant association with unsuccessful treatment outcomes based on the results of the bivariate Cox regression analysis (HR=0.823; 95% CI: 0.558-1.216; p=0.329) and the multivariate Extended Cox regression analysis (after adjusting for covariate variables). The survival probability between the group with severe adverse reactions and the non- severe adverse reactions group did not differ significantly.
Conclusion: Monitoring adverse drug reactions during DR TB treatment is crucial to support the success of the treatment.