

# Kekerapan Hiperpigmentasi Kulit Akibat Efek Samping Klofazimin pada Pengobatan Tuberkulosis Resistan Obat Di RSUP Persahabatan = Prevalence Of Skin Hyperpigmentation Due To Adverse Events Of Clofazimine In The Treatment Of Drug-Resistant Tuberculosis At Persahabatan Hospital

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## Abstrak

**Latar Belakang:** Tuberkulosis resistan obat (TB RO) masih menjadi masalah kesehatan utama di dunia. Tahun 2020 secara global terdapat 157.903 kasus TB Multi Drug Resistant/Rifampicin Resistant (MDR/RR) terdeteksi dan ternotifikasi, 95% dilakukan enrollment, namun angka keberhasilan pengobatan TB RR/MDR sebesar 59% dan TB XDR sebesar 52%, sedangkan di Indonesia terdapat 8.268 kasus TB RR/MDR, 52% dilakukan enrollment namun angka keberhasilan pengobatan TB RR/MDR sebesar 47% dan TB XDR 30%. Tahun 2020, Klofazimin (CFZ) merupakan salah satu bagian grup B pengobatan TB RO tanpa injeksi pada paduan jangka pendek dan jangka panjang. Terdapat beberapa efek samping dalam penggunaan CFZ salah satunya adalah hiperpigmentasi kulit. Penelitian ini bertujuan untuk mengetahui kekerapan, karakteristik subjek, awitan, durasi, dan derajat hiperpigmentasi kulit akibat CFZ serta faktor apa saja yang berhubungan pada pengobatan TB RO di RSUP Persahabatan. **Metode:** Desain penelitian ini adalah kohort retrospektif menggunakan data rekam medis pasien, dilakukan di Poli TB RO RSUP Persahabatan Juli 2021-Mei 2022, dengan teknik total sampling. Subjek penelitian adalah pasien TB RO yang mendapatkan CFZ di Poli TB RO di RSUP Persahabatan yang memulai enrollment pada tahun 2019-2020 yang memenuhi kriteria penelitian. Hiperpigmentasi kulit dinilai dari anamnesis bulanan setiap pasien kontrol. **Hasil:** Didapatkan 429 subjek penelitian dengan kekerapan hiperpigmentasi kulit pada 48 subjek (11,18%). Karakteristik subjek usia 41 (1878) tahun, 58% laki-laki, 48% dengan gizi kurang dan normal, 25,2% komorbid DM tipe 2 dan 2,8% komorbid HIV, durasi pengobatan 285 (1860) hari, kasus terbanyak TB RR/MDR sebesar 89,3%, dan luaran semuh sebesar 47%. Efek samping hiperpigmentasi kulit didapatkan dengan median awitan 31 (28168) hari pengobatan dan hingga pengobatan selesai efek samping hiperpigmentasi kulit masih didapatkan (belum reversibel). **Kesimpulan:** Terdapat hubungan antara efek samping hiperpigmentasi kulit dengan durasi pengobatan ( $p=<0,001$ ) yakni hari ke 344 (70769) dan paduan jangka pendek oral dan jangka pendek injeksi ( $p=<0,001$ ) dengan RR 10,100 (5,05920,166).

.....**Background:** Drug-resistant tuberculosis (DR TB) is still a major health problem in the world. In 2020 globally there were 157,903 cases of Multi Drug Resistant/Rifampin Resistant (MDR/RR) TB detected and notified, 95% were enrolled, but the treatment success rate for RR/MDR TB was 59% and XDR TB was 52%, while in Indonesia there were Of the 8,268 cases of RR/MDR TB, 52% underwent enrollment but the success rate of RR/MDR TB treatment was 47% and 30% XDR TB. In 2020, Clofazimine (CFZ) is part of group B RO-TB treatment without injection in short-term and long-term combinations. There are several side effects in using CFZ, one of which is skin hyperpigmentation. This study aims to determine the frequency, subject characteristics, onset, duration, and degree of skin hyperpigmentation due to CFZ and what factors are related to the treatment of DR TB at Persahabatan Hospital. **Methods:** The design of this study was a retrospective cohort using patient medical record data, carried out at the DR TB clinic

Persahabatan Hospital from July 2021-May 2022, with a total sampling technique. The research subjects were DR TB patients who received CFZ at the DR TB clinic at the Persahabatan Hospital who started enrollment in 2019-2020 who met the research criteria. Skin hyperpigmentation was assessed from the monthly history of patient. Results: There were 429 subjects who received CFZ with frequent skin hyperpigmentation in 48 subjects (11.18%). Subject's characteristics are 41 (1878) years old, 58% male, 48% with malnutrition and normal, 25.2% comorbid type 2 DM and 2.8% comorbid HIV, duration of treatment 285 (1860) days, the most cases of RR/MDR TB were 89.3%, and the outcome recovered was 47%. The side effect of skin hyperpigmentation was obtained with a median onset of 31 (28168) days of treatment and until the end of treatment the side effect of skin hyperpigmentation was still found (not reversible). Conclusion: There is a relationship between side effects of skin hyperpigmentation with treatment duration ( $p=<0.001$ )m i.e. day 344 (70769) and short-term oral and short-term injection ( $p=<0.001$ )f with RR 10.100 (5.05920.166).