



## INTISARI

Terapi antiretroviral (ARV) dapat meningkatkan harapan hidup ODHA (Orang dengan HIV/AIDS). Rejimen ARV yang tersedia di Indonesia adalah rejimen ARV lini pertama dan kedua. Jika terjadi kegagalan terapi dan toksisitas berat terhadap ARV lini pertama, maka dilakukan *switch* atau mengubah rejimen ARV lini pertama ke lini kedua. Penelitian mengenai keamanan dan luaran terapi ARV lini kedua belum banyak dilakukan di Indonesia. Penelitian ini bertujuan untuk mengetahui gambaran kejadian efek samping dan potensi interaksi obat ARV lini kedua, serta perbandingan luaran terapi rejimen terapi ARV lini kedua pada pasien HIV/AIDS.

Penelitian ini menggunakan rancangan penelitian studi kohort retrospektif. Pengambilan data penelitian dilakukan secara retrospektif selama periode Januari 2008 s.d. Desember 2017 di RSUP Dr. Kariadi Semarang. Jumlah sampel penelitian untuk gambaran efek samping dan potensi interaksi obat sebanyak 73 pasien, sedangkan untuk perbandingan luaran terapi sebanyak 42 pasien. Data yang diperoleh kemudian dilakukan analisis deskriptif dan analisis komparatif di antara rejimen ARV lini kedua. Analisis komparatif rejimen berdasarkan perubahan kadar CD4 menggunakan uji *Kruskal-Wallis*, analisis komparatif rejimen berdasarkan kejadian infeksi oportunistik dan ketahanan hidup menggunakan uji *Fisher*.

Efek samping ARV lini kedua terjadi pada 7 pasien (9,59%). Rejimen yang paling banyak menyebabkan efek samping adalah rejimen TDF+3TC+LPV/r (42,86%). Gejala efek samping yang muncul antara lain muntah-muntah (14,29%), mual (14,29%), diare (14,29%), gatal-gatal (14,29%), neuropati perifer (28,58%), dan lipodistrofi (14,29%). Sebanyak 34 potensi kejadian interaksi obat yang signifikan ditemukan pada 28 pasien (38,36%). Obat yang berpotensi terjadi interaksi antara lain rifampisin, simvastatin, atorvastatin, fenitoin, flukonazol, domperidon, dan metilergometrin. Setelah 6 bulan pengobatan ARV lini kedua, terdapat peningkatan kadar CD4 ( $P<0,05$ ), sebanyak 37 pasien (88,10%) tidak mengalami infeksi oportunistik baru atau berulang, dan sebanyak 41 pasien (97,62%) masih bertahan hidup. Tidak terdapat perbedaan di antara ketiga rejimen ARV lini kedua (ZDV+3TC+LPV/r, TDF+3TC+LPV/r, TDF+FTC+LPV/r) dalam meningkatkan kadar CD4 serta menurunkan kejadian infeksi oportunistik dan kematian setelah 6 bulan pengobatan ARV lini kedua.

**Kata kunci : HIV/AIDS, antiretroviral lini kedua, luaran terapi, efek samping, interaksi obat**



## **ABSTRACT**

Antiretroviral (ARV) can increase life expectancy of people living with HIV/AIDS. The ARV regimens available in Indonesia are first and second-line ARV regimens. When treatment failure and severe toxicity to first-line antiretroviral drugs occurs, it is recommended to switch or change the first-line ARV regimens to the second-line. Research on the safety and outcome of second-line ARV has not been widely conducted in Indonesia. This study aims to know the overview of adverse events and potential drug interactions among second-line ARV, and also to compare treatment outcomes among second-line ARV regimens in HIV/AIDS patients.

This is a retrospective cohort study. The data were collected retrospectively from medical records during January 2008 until December 2017 at Dr. Kariadi General Hospital Semarang. The number of samples for side-effects and potential drug interaction were 73 patients, while for comparison of treatment outcomes were 42 patients. The data obtained were then analyzed descriptively and comparatively among second-line ARV regimens. Comparative analysis of regimens based on changes in CD4 levels using the Kruskal-Wallis test, comparative analysis based on the incidence of opportunistic infections and survival using the Fisher test.

Second-line ARV side effects occurred in 7 patients (9,59%). Regimen that cause the most side effect is TDF+3TC+LPV/r (42,86%). Symptoms of side effect include vomiting (14,29%), nausea (14,29%), diarrhea (14,29%), itching (14,29%), peripheral neuropathy (28,58% ), and lipodystrophy (14,29%). A total of 34 potential significant drug interaction events occurred in 28 patients (38,36%). Drugs that have high potency of drug interaction include rifampicin, simvastatin, atorvastatin, phenytoin, fluconazole, domperidone, and methylergometrine. After 6 months of second-line ARV treatment, there was an increase in CD4 cell count ( $P <0.05$ ), 37 patients (88,10%) did not experience new or recurrent opportunistic infections, and 41 patients (97,62%) survived. There was no difference among the three second-line ARV regimens (ZDV+3TC+LPV/r, TDF+3TC+LPV/r, TDF+FTC+LPV/r) in increasing the CD4 count and decreasing the incidence of opportunistic infections and death after 6 months of second-line ARV treatment.

**Keywords :** HIV/AIDS, second-line antiretroviral, therapeutic outcome, side effect, drug interaction