

Evaluasi efektivitas dan efek samping obat antituberkulosis kategori 1 kombinasi dosis tetap dan dosis lepasan pada pasien tuberkulosis paru konfirmasi bakteriologis di rumah sakit TNI AU Dr Esnawan Antariksa Halim Perdanakusuma. = Effectiveness and adverse drug reactions evaluation of fixed dose combination versus separate formulations antituberculosis in bacteriological confirmed tuberculosis patients in air force military Dr Esnawan Antariksa Halim Perdanakusuma hospital

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Abstrak

Pendahuluan : Walaupun pemerintah Indonesia sudah menetapkan program Direct Observed Treatment Short course DOTS dengan Obat Antituberkulosis OAT kombinasi dosis tetap KDT, masih ditemukan kasus tuberkulosis TB baru di Indonesia. Informasi tentang perbedaan efektivitas dan efek samping OAT KDT dan OAT dosis lepasan pada fase intensif dan fase lanjutan masih merupakan suatu perdebatan. Penelitian ini bertujuan untuk membandingkan efektivitas dan efek samping OAT KDT dengan OAT dosis lepasan pada pasien TB paru kasus baru konfirmasi bakteriologis dan mengevaluasi penggunaan fase sisipan pada kedua kelompok OAT.

Metode : Penelitian retrospektif observasional ini menggunakan data sekunder dari rekam medis pasien TB paru kasus baru konfirmasi bakteriologis yang mendapat pengobatan OAT kategori 1 KDT atau OAT dosis lepasan dalam periode 1 Januari 2014 sampai dengan 31 Januari 2017. Efektivitas dinilai dari konversi basil tahan asam BTA pada akhir bulan ke 2 dan akhir bulan ke 6, serta evaluasi penggunaan fase sisipan pada akhir bulan ke 3. Efek samping dinilai dari efek samping obat ESO mayor dan minor yang timbul selama pemakaian OAT KDT atau dosis lepasan. Perbedaan efektivitas dinilai dengan Chi square.

Hasil : Data pasien yang mendapat OAT KDT 33 orang dan OAT dosis lepasan 30 orang selama periode 1 Januari 2014 hingga 31 Januari 2017 di RS Dr Esnawan Antariksa Halim Perdanakusuma Jakarta di evaluasi. Pada akhir fase intensif, proporsi pasien pada kelompok OAT KDT dan lepasan yang mengalami konversi BTA tidak berbeda bermakna 78,8 vs 83,3, $p=0,693$. Pada akhir fase sisipan, 100 pasien kelompok OAT lepasan mengalami konversi, satu pasien 14,3 pada kelompok KDT gagal konversi dan dikeluarkan dari penelitian ini. Semua pasien yang menyelesaikan fase lanjutan pada kedua kelompok mengalami konversi BTA. ESO mayor berupa hepatitis dan reaksi sensitivitas ditemukan lebih banyak pada kelompok KDT dibandingkan lepasan 6,1 vs 0. ESO minor juga lebih banyak ditemukan pada kelompok KDT dibandingkan lepasan 30,3 vs 23,3. Efek samping minor yang paling banyak dialami adalah nyeri perut dan mual. Proporsi subjek yang mengalami ESO lebih banyak pada kelompok KDT dibandingkan kelompok lepasan 33,3 vs 23,3.

Kesimpulan : Tidak terdapat perbedaan efektivitas dan efek samping OAT kategori 1 KDT dibanding dosis lepasan pada fase intensif dan lanjutan. Terdapat keberhasilan konversi pada akhir fase sisipan pada kedua kelompok OAT.

Introduction : Even though Indonesian Government has established Direct Observed Treatment Short Course DOTS program with fixed dose combination FDC Antituberculosis, new tuberculosis cases continue to occur. Information on differences in effectiveness and adverse drug reactions ADRs of FDC and separate

formulations persists. This study aimed to evaluate the effectiveness and adverse drug reactions of FDC versus separate antituberculosis formulations in new onset bacteriological confirmed pulmonary TB patients and to evaluate the effect of one month extension of intensive phase in both groups.

Methods : A retrospective observational study was conducted using patient data records. All new onset pulmonary TB patients with recorded bacteriological confirmation and received first category FDC or separate antituberculosis formulations during January 1st 2014 until January 31st 2017 period were included. Effectiveness outcome were determined by Acid fast bacilli sputum smear conversion at the end of intensive phase month 2 and month 6 of therapy, and evaluation of extended phase at the end of month 3. Major and minor ADRs occurred during antituberculosis treatment were considered as ADRs outcome. The difference on acid bacilli sputum conversions between two groups were analyzed using Chi Square test.

Results : Patients treated with FDC n 33 and with separate formulations n 30 during January 1st 2014 to January 31st 2017 at dr. Esnawan Antariksa Hospital, Halim perdanakusuma Jakarta were evaluated. The rate of sputum smear conversions at the end of intensive phase was not significantly higher in separate formulations group as compared with FDC group 83,3 vs 78,7 ,p 0,693 . The intensive phase was extended one more month for patients with conversion failure at month 2, at the end of extended intensive phase, 100 of separate formulation were conversion. One patient 14,3 in FDC group did not gain sputum conversion during the extended phase and was considered as medication failure and being excluded from the study. At the end of continuation phase, sputum smear conversions were achieved by all patients in both groups. Major ADRs hepatitis and hypersensitivity reactions were found higher in FDC group as compared with separate formulations group 6.1 vs 0 . Minor ADRs also were found higher in FDC group 30.3 vs 23.3 . The most frequently occurred ADRs were abdominal discomfort and nausea. The proportion of subjects with ADRs were higher in FDC than separate formulation group 33,3 vs 23,3.

Conclusion : There were no differences in the effectiveness and safety profile of the first category FDC and separate antituberculosis formulations. Successful conversions occurred at the end of the extended intensive phase in both groups.