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 programDirect Observed Treatment Short course DOTS dengan ObatAntituberkulosis OAT kombinasi dosis tetap KDT , masih ditemukan kasustuberkulosis TB baru di Indonesia. Informasi tentang perbedaan efektivitasdan efek samping OAT KDT dan OAT dosis lepasan pada fase intensif danfase lanjutan masih merupakan suatu perdebatan. Penelitian ini bertujuan untukmembandingkan efektivitas dan efek samping OAT KDT dengan OAT dosislepasan pada pasien TB paru kasus baru konfirmasi bakteriologis danmengevaluasi penggunaan fase sisipan pada kedua kelompok OAT.
Metode : Penelitian retrospektif observasional ini menggunakan datasekunder dari rekam medis pasien TB paru kasus baru konfirmasibakteriologis yang mendapat pengobatan OAT kategori 1 KDT atau OAT dosislepasan dalam periode 1 Januari 2014 sampai dengan 31 Januari 2017.Efektivitas dinilai dari konversi basil tahan asam BTA pada akhir bulan ke 2dan akhir bulan ke 6, serta evaluasi penggunaan fase sisipan pada akhir bulanke 3. Efek samping dinilai dari efek samping obat ESO mayor dan minoryang timbul selama pemakaian OAT KDT atau dosis lepasan. Perbedaanefektivitas dinilai dengan Chi square.
Hasil : Data pasien yang mendapat OAT KDT 33 orang dan OAT dosislepasan 30 orang selama periode 1 Januari 2014 ndash; 31 Januari 2017 di RS drEsnawan Antariksa Halim Perdanakusuma Jakarta di evaluasi. Pada akhir faseintensif, proporsi pasien pada kelompok OAT KDT dan lepasan yangmengalami konversi BTA tidak berbeda bermakna 78,8 vs 83,3 , p=0,693 .Pada akhir fase sisipan, 100 pasien kelompok OAT lepasan mengalamikonversi, satu pasien 14,3 pada kelompok KDT gagal konversi dandikeluarkan dari penelitian ini. Semua pasien yang menyelesaikan fase lanjutanpada kedua kelompok mengalami konversi BTA. ESO mayor berupa hepatitisdan reaksi sensitivitas ditemukan lebih banyak pada kelompok KDTdibandingkan lepasan 6.1 vs 0 . ESO minor juga lebih banyakditemukan pada kelompok KDT dibandingkan lepasan 30.3 vs 23.3 . Efeksamping minor yang paling banyak dialami adalah nyeri perut dan mual.Proporsi subjek yang mengalami ESO lebih banyak pada kelompok KDTdibandingkan kelompok lepasan 33,3 vs 23,3.
Kesimpulan : Tidak terdapat perbedaan efektivitas dan efek samping OATkategori 1 KDT dibanding dosis lepasan pada fase intensif dan lanjutan. Terdapat keberhasilan konversi pada akhir fase sisipan pada kedua kelompokOAT.
<hr><i>Introduction : Eventhough Indonesian Government has established DirectObserved Treatment Short Course DOTS program with fixed dosecombination 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 theeffectiveness and adverse drug reactions of FDC versus separateantituberculosis formulations in new onset bacteriological confirmedpulmonary TB patients and to evaluate the effect of one month extension ofintensive phase in both groups.
Methods : A retrospective observational study was conducted using patientdata records. All new onset pulmonary TB patients with recordedbacteriological confirmation and received first category FDC or separate antituberculosis formulations during January 1st 2014 until January 31st 2017 period were included. Efectiveness outcome were determined by Acid fastbacilli sputum smear conversion at the end of intensive phase month 2 andmonth 6 of therapy, and evaluation of extended phase at the end of month 3.Major and minor ADRs occured during antituberculosis treatment wereconsidered 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 Januari 31st 2017 at dr. Esnawan AntariksaHospital, Halim perdanakusuma Jakarta were evaluated. The rate of sputumsmear conversions at the end of intensive phase was not significantly higher inseparate 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 withconversion failure at month 2, at the end of extended intensive phase, 100 of separate formulation were convertion. One patient 14,3 in FDC group didnot gain sputum conversion during the extended phase and was considered asmedication failure and being excluded from the study. At the end ofcontinuation phase, sputum smear conversions were achieved by all patients inboth groups. Major ADRs hepatitis and hypersensitivity reactions were foundhigher in FDC group as compared with separate formulations group 6.1 vs0 . 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 separateformulation 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.Successfulconversions occured at the end of the extended intensive phase in both groups.</i>