Penilaian Efektivitas dan Keamanan Favipiravir pada Pasien COVID-19 di RSUD Tarakan Jakarta = The Effectiveness and Safety Assessments of Favipiravir on COVID-19 Patients at Tarakan Jakarta District Hospital

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Abstrak

Favipiravir adalah obat antivirus yang diberikan izin penggunaan darurat oleh BPOM RI untuk pengobatan COVID-19. Penelitian ini bertujuan untuk mengevaluasi efektivitas favipiravir berdasarkan perbaikan klinis pasien dan menilai keamanan favipiravir berdasarkan reaksi obat yang tidak dikehendaki pada pasien COVID-19 di RSUD Tarakan Jakarta menggunakan algoritma Naranjo. Desain penelitian ini adalah kohort retrospektif dengan pengumpulan data sekunder dari rekam medis pasien. Berdasarkan pengambilan sampel secara konsekutif, didapatkan sampel penelitian sebanyak 105 pasien COVID-19 yang menerima favipiravir dan 105 pasien COVID-19 yang menerima oseltamivir pada periode Agustus – Desember 2020. Hasil penelitian menunjukkan bahwa kelompok pasien yang menerima favipiravir mengalami perbaikan klinis yang lebih baik dibandingkan kelompok pasien yang menerima oseltamivir (57,9% vs 42,1%; RR = 1,378; 95% CI = 1,049-1,809; p = 0,027). Tidak ada ROTD yang serius dari penggunaan favipiravir yang teramati pada pasien. ROTD yang teramati adalah diare (1,9%), hiperurisemia (5,7%), insomnia (1,9%), mual (5,7%), mual dan muntah (1,9%), nyeri ulu hati (1,9%), peningkatan ALT (6,7%), peningkatan AST (2,9%), penurunan jumlah neutrofil (1,0%), sakit kepala (9,5%), dan sakit perut (3,8%). Hasil analisis kausalitas menunjukkan bahwa 5 kasus hiperurisemia, 3 kasus peningkatan ALT, 2 kasus peningkatan AST, dan 1 kasus penurunan jumlah neutrofil merupakan ROTD dengan kategori “mungkin” dalam skala probabilitas Naranjo. Kesimpulannya, favipiravir lebih efektif dibandingkan oseltamivir dan memiliki profil keamanan yang baik pada pasien COVID-19.

.....Favipiravir is an antiviral drug that was granted an emergency use authorization by BPOM RI for the treatment of COVID-19. This study aimed to evaluate the effectiveness of favipiravir based on the patient’s clinical improvement and to assess the safety of favipiravir by adverse drug reactions on COVID-19 patients at Tarakan Jakarta District Hospital using the Naranjo algorithm. The design of this study was a retrospective cohort with secondary data collection from the patient medical records. Based on the consecutive sampling, the study samples were 105 COVID-19 patients who received favipiravir and 105 COVID-19 patients who received oseltamivir in the period of August – December 2020. The results showed that the group of patients who received favipiravir had better clinical improvement than the group of patients who received oseltamivir (57.9% vs 42.1%; RR = 1.378; 95% CI = 1.049-1.809; p = 0.027). No serious ADR from the use of favipiravir was observed on patients. ADRs observed were diarrhea (1.9%), hyperuricemia (5.7%), insomnia (1.9%), nausea (5.7%), nausea and vomiting (1.9%), heartburn (1.9%), elevated ALT (6.7%), elevated AST (2.9%), low neutrophil count (1.0%), headache (9.5%), and abdominal pain (3.8%). The results of causality analysis showed that 5 cases of hyperuricemia, 3 cases of elevated ALT, 2 cases of elevated AST, and 1 case of low neutrophil count were ADRs with a “probable” category in the Naranjo probability scale. In conclusion, favipiravir is more effective than oseltamivir and has a good safety profile on COVID-19 patients.