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Studi Farmakovigilans : Penggunaan Obat Kategori *Off-Label* di RSU PKU
Muhammadiyah Bantul Yogyakarta

INTISARI

Latar Belakang : Obat *off-label* adalah obat yang diresepkan dan digunakan di luar ketentuan izin edar berkaitan dengan dosis, rute pemberian, usia, indikasi, dan kontraindikasi. Studi farmakovigilans dilakukan untuk mendeteksi dan menilai kausalitas guna mencegah *Adverse Drug Reaction* (ADR) terkait penggunaan obat *off-label*. Tujuan penelitian ini adalah mengetahui profil penggunaan obat *off-label* dan studi farmakovigilans di RSU PKU Muhammadiyah Bantul Yogyakarta.

Metode Penelitian : Penelitian ini menggunakan metode observasional deskriptif dengan pengambilan data secara *cohort* prospektif. Data efek samping obat *off-label* yang merupakan bagian dari studi farmakovigilans diperoleh dengan *in-depth interview* pada 63 pasien inklusi. Penilaian kausalitas penggunaan obat dengan *adverse drug reaction* (ADR) menggunakan sistem *World Health Organization-Uppsala Monitoring Centre* (WHO-UMC).

Hasil : Studi pada 63 resep didapatkan obat *off-label* sebanyak 117 obat atau 36% dari 322 total penggunaan obat. Penggunaan obat *off-label* pada penelitian ini diperoleh 3 klasifikasi *off-label* dari 63 resep yaitu 27 kasus *off-label* usia, 33 kasus *off-label* indikasi, 1 kasus *off-label* rute pemberian, 1 kasus *off-label* indikasi dan rute pemberian, serta 1 kasus *off-label* usia dan indikasi. Hasil telaah efek samping obat ditemukan 23 resep atau 37% pasien mengalami efek samping obat. Penilaian kausalitas menunjukkan hampir seluruh kejadian efek samping obat *off-label* berhubungan dengan obat. Terdapat 1 peresepan yang belum pasti berhubungan dengan obat yaitu keluhan pusing pada pasien yang diresepkan bisoprolol.

Kesimpulan : Hasil penelitian menunjukkan dari 63 resep didapatkan obat *off-label* sebanyak 36% dari total penggunaan obat dengan 23 resep atau 37% pasien mengalami efek samping yang berhubungan dengan penggunaan obat *off-label*.

Kata kunci : Farmakovigilans, Obat *Off-label*, *Adverse Drug Reaction* (ADR)

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Pharmacovigilance Study: Use of Off-Label Drugs at PKU Muhammadiyah Hospital, Bantul Yogyakarta

ABSTRACT

Background : Off-label drugs are drugs that are prescribed and used outside of the marketing authorization with regard to dosage, route of administration, age, indications, and contraindications. Pharmacovigilance studies were conducted to detect and assess causality in order to prevent Adverse Drug Reaction (ADR) related to off-label drug use. The purpose of this study was to determine the profile of off-label drug use and pharmacovigilance studies at PKU Muhammadiyah Hospital, Bantul, Yogyakarta.

Methods : This study used a descriptive observational method with prospective cohort data collection. Data on side effects of off-label drugs that are part of the pharmacovigilance study were obtained by in-depth interviews with 63 included patients. Assessment of causality of drug use with adverse drug reaction (ADR) using the World Health Organization-Uppsala Monitoring Center (WHO-UMC) system.

Result : A study of 63 prescriptions found 117 off-label drugs or 36% of the total 322 drug use. The use of off-label drugs in this study resulted in 3 off-label classifications from 63 prescriptions, namely 27 cases of off-label age, 33 cases of off-label indication, 1 case of off-label route of administration, 1 case of off-label indication and route of administration, and 1 case of off-label age and indication. The results of the study of drug side effects found 23 prescriptions or 37% of patients experienced drug side effects. The causality assessment showed that almost all the incidence of off-label drug side effects were drug-related. There is 1 prescription that is not sure related to the drug, namely complaints of dizziness in patients who are prescribed bisoprolol.

Conclusion : The results showed that from 63 prescriptions, 36% of the total drug use was off-label, with 23 prescriptions or 37% of patients experiencing side effects related to the use of off-label drug.

Keywords : Pharmacovigilance, Off-label Drug, Adverse Drug Reaction (ADR)