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Clinical Features of Drug Eruption in An Indonesian Tertiary Hospital

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Abstract

Drug eruption is a response to drugs undergoing sensitization, which is mediated by the immune system. Clinical features of drug eruptions, such as maculopapular drug eruption, Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), are known as common drug reactions. This study aimed to explore the characteristics and clinical features of patients with drug eruptions at the Department of Dermatology and Venereology of Dr. Hasan Sadikin General Hospital, Bandung, Indonesia. This retrospective descriptive study used data from the department from patients treated between January 1, 2014 and December 31, 2018. Data were analyzed using Excel and SPSS software. In this study, 200 subjects were included, mainly consisting of female subjects (50.5%) and aged between 19 and 65 (89%). Maculopapular drug eruption (45%) was the most typical clinical presentation, followed by SJS/TEN (37.5%), and DRESS (3%). The analgesics and non-steroidal anti-inflammatory drugs (NSAID) group was the most commonly suspected causative drug (36.91%), with paracetamol (29.18% of total drugs consumed) as the most frequent NSAID causing the eruption. This was followed by the antibiotic-type drugs group (36.48%), with cotrimoxazole (9.87% of total drugs consumed) as the most common one. So, maculopapular drug eruption is the most common clinical presentation of drug eruption, with analgesics and non-steroidal anti-inflammatory drugs (NSAID) class as the most suspected causative drug. Further investigations are needed to get the accurate result.

Keywords: Clinical features, drug eruption, maculopapular drug eruption, non-steroidal anti-inflammatory drugs (NSAID)

Introduction

Adverse drug reaction (ADR) is a dangerous, undesirable, and unpredictable effect caused by using a drug that is intended for prevention, diagnosis, or treatment. Adverse Drug Reactions are divided into two categories, namely type A and type B. Drug eruption is one of the B-type reactions from ADR.[1] Drug eruption is a response mediated by the immune system to drugs undergoing a sensitization process.[2] Incidence of drug eruption in hospitals is 0.1% to 2% of hospitalized patients.[3] Clinical features arising from drug eruptions include urticaria, maculopapular, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), Drug reaction with eosinophilia and systemic symptoms (DRESS).[4]

Clinical features can be used as a diagnostic approach in patients with drug eruptions if there are hypersensitivity reactions, signs and symptoms, skin morphology, and clear laboratory tests. Not infrequently, the clinical picture sometimes produces negative results because many types of drugs are consumed simultaneously, and each type of drug produces different reactions, so it can only occasionally be relied upon. Additional investigations, such as skin prick and provocation tests, are needed.[5]

The most recent research and literature studies on the clinical features of drug eruption at Dr. Hasan Sadikin General Hospital, Bandung, have yet to be found. Proper identification and anamnesis of the cause of drug reactions is one important thing to provide fast and appropriate management for patients, with the aim of

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improving prognosis and reducing morbidity rates. Thus, this condition encourages the authors to research the clinical picture of drug eruption at Dr. Hasan Sadikin General Hospital, Bandung, from 2014 to 2018.

Methods

This research was conducted using a retrospective descriptive method using data from the Department of Dermatology and Venereology at Dr. Hasan Sadikin General Hospital, Bandung, on January 1st, 2014, and December 31st, 2018. The number of subjects was determined by the total sampling method. The inclusion criteria were complete data on drug eruption patients (age, gender, number of drugs consumed, clinical features, and drug type). Exclusion criteria were drug eruption patients' data that were incomplete, inaccessible, and duplicate data. The Ethics Committee of Universitas Padjadjaran Bandung approved this study with the number 679/UN6.KEP/EC/2019.

The data was collected using Microsoft® Excel 2021 and processed in table form, with percentages determined and unique codes created for statistical analysis. The statistical analysis was performed by IBM® SPSS® 26th version using the Spearman rho test to determine the correlation and strength of correlation between two variables.[6,7]

Results

During the study, a total of 200 subjects met the inclusion criteria. Table 1 shows the characteristics of drug eruption patients. Based on gender, most research subjects were female, and there were as many as 101 patients (50.5%). On the other hand, drug eruptions are most affected at ages 19-65 years (adults) (178 patients, 89%) and taking only one drug (107 patients; 53.5%). Statistical analysis shows that age, gender, and number of drugs have weak and no significant correlation with drug eruption.

Table 2 shows the clinical features of drug eruption from data obtained from the Department of Dermatology and Venereology at Dr. Hasan Sadikin General Hospital, Bandung. The most common clinical feature was maculopapular in 90 patients (45%). Stevens-Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN) was the second most common clinical feature in 75 patients (37.5%), followed by Drug reaction with eosinophilia and systemic symptoms (DRESS) in 6 patients (3%).

Table 3 shows a cross-tabulation of clinical features with causative drug classes. There are four classes of drugs, namely antibiotics, NSAIDs and analgesics, antiretrovirals and anticonvulsants and several other drugs

Table 1 Drug Eruption Patient Characteristics

Characteristics	Subject (n=200)		Spearman Rho Test	
	n	%	Correlation Coefficient	Significant
Age			-0.123	0.084
Baby (0-2 years)	-	-		
Kids (2-18 years)	12	6		
Adults (19-65 years)	178	89		
Old Adults (>65 years)	10	5		
Gender			-0.012	0.871
Female	101	50.5		
Male	99	49.5		
Number of Drugs Consumed			0.003	0.962
One Drug	107	53.5		
Two Drugs	60	30		
Three Drugs	16	8		
>Three Drugs		17	8.5	

Table 2 Clinical Features of Drug Eruption

Clinical Features	Subject (n=200)	
	n	%
Maculopapular	90	45
Stevens-Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN)	75	37.5
Drug reaction with eosinophilia and systemic symptoms (DRESS)	6	3
Fixed Drug Eruption	11	5.5
Erythroderma	8	4
Acute generalized exanthematous pustulosis (AGEP)	7	3.5
Angioedema	2	1
Urticaria	1	0.5

such as antiuricemia (allopurinol), antifungal (fluconazole), antidyslipidemia (simvastatin), cardiovascular drugs (amlodipine, amiodarone, captopril, procardio), antianxiety (alprazolam), gastrointestinal disturbances (metoclopramide, ranitidine, lanzoprazole), antithyroid medications (propylthiouracil /PTU and NPTU), chemotherapy (hydrea, methotrexate), common-cold remedies (pseudoephedrine, guaifenesin), antimalarial (chloroquine) and antivertigo medications (betahistine mesylate). The most suspected drug group that caused drug eruptions were analgesics and non-steroidal anti-inflammatory drugs (NSAID) group used alone or with other drugs in 86 patients (36.91%), followed by antibiotic-type drugs used alone or with other drugs in 85 patients (36.48%). Based on the type of drug consumed, the drug most suspected of drug eruptions was paracetamol taken alone or together with other drugs in 68 patients (29.18%), followed by co-trimoxazole taken alone or together with other drugs in 23 patients (9.87%), and antituberculosis drugs (ATD) which were consumed alone or together with other drugs in 19 patients (8.15%).

Discussion

Drug eruption hypersensitivity reactions are divided into immediate reactions (acute) and non-immediate reactions (delayed).[2] Immediate reactions are mediated by IgE antibody or non-specific histamine release.[8] IgE antibodies will bind with FcRI on mast cells and basophil surfaces and form a binding place multivalent to drug antigens. Then hapten-protein complex antigens will cross-link with IgE and stimulate the release of mediators such as histamine, tryptase, and TNF-α and produce new mediators such as leukotrienes, prostaglandins, kinins, and other cytokines. Clinical features caused by this reaction are urticaria, angioedema, and anaphylactic shock.[4]

Non-immediate reactions are reactions mediated by T lymphocytes.[4] These reactions are divided based on the type of cytokines produced by T lymphocytes and immune cells stimulated by these cytokines, such as eosinophils and neutrophils.[9] In normal circumstances, antigens will be phagocyted by dendritic cells, carried to lymph nodes, and stimulated by cytokines such as eosinophils and neutrophils to be presented to Naive T cells. Specific pathogen T cells can be directly stimulated in some drug antigens and migrate to the target organ. When re-exposed to the drug antigens, specific pathogenic T cells will be activated and secrete cytokines such as perforin, granzymes, and granulysin to damaged tissues. This reaction will cause clinical symptoms such as maculopapular exanthema, drug reaction with eosinophilia and systemic symptoms, Stevens-Johnson Syndrome (SSJ), toxic epidermal necrolysis (TEN), acute generalized pustular exanthematous (AGEP), pustular exanthema, and eczema.[4]

The results of this study indicated that of 200 drug eruption patients, mostly were female in 101 patients (50.5%) and ages ranging from 19 – 65 years (adults), being the most affected age group in 178 patients (89%). These results were similar to the study from Farshchian et al.[10], which said that the number of women who experienced drug eruption was 194 patients (63%) compared to men, which were 114 patients (37%) with an average age of 35.2 ± 16.8. Another study by Garg et al.[11] also stated that there were more adults than children and

Table 3 Clinical Features with Suspected Drug Type Cases

Drug Type	Clinical Features								TOTAL	%
	Urticaria	Angioedema	Erythroderma	Maculopapular	Fixed drug eruption	AGEP	DRESS	SJS/ TEN		
Antibiotic									85	36.48
Ciprofloxacin		1		2				1	4	1.72
Ceftriaxone				1					1	0.43
Cotrimoxazole			1	13	2			7	23	9.87
Cefadroxil				9		2	1	1	13	5.58
Cefixime				2		1		1	4	1.72
Ampicillin								1	1	0.43
Amoxicillin			1	3		1		3	8	3.43
ATD	1		1	11	2		1	3	19	8.15
Streptomycin								1	1	0.43
Moxifloxacin				1					1	0.43
Erythromycin				1					1	0.43
Thiamphenicol		1							1	0.43
Meropenem			1						1	0.43
Clindamycin				1			1		2	0.86
Amoxiclav								1	1	0.43
Levofloxacin								1	1	0.43
Minocycline				1					1	0.43
Clofazimine				1					1	0.43
Chloramphenicol						1			1	0.43
Analgesic and NSAID									86	36.91
Mefenamic Acid					1			1	2	0.86
Methampyrone								2	2	0.86
Piroxicam				1					1	0.43
Paracetamol			1	22	3	3	2	37	68	29.18

Table 3 Continued

Drug Type	Clinical Features								TOTAL	%
	Urticaria	Angioedema	Erythroderma	Maculopapular	Fixed drug eruption	AGEP	DRESS	SJS/ TEN		
Meloxicam				1	2			1	4	1.72
Ibuprofen			1	2					3	1.29
Hufagesic								1	1	0.43
Na-Diclofenac		1		1	1			1	4	1.72
Ketolorac				1					1	0.43
Antiretroviral									25	10.73
Evafirenz				6					6	2.58
Nevirapine				5				2	7	3.00
Lamivudine				4	1			2	7	3.00
Tenofovir				1					1	0.43
Duviral				1				1	2	0.86
Abacavir								1	1	0.43
Emtricitabine				1					1	0.43
Anticonvulsant									15	6.44
Phenytoin			1	1				1	3	1.29
Lamotrigine								1	1	0.43
Carbamazepine				3				8	11	4.72
Others									22	9.44
Allopurinol							1	1	2	0.86
Pseudoephedrine								1	1	0.43
Amlodipine				1					1	0.43
Metoclopramide			1						1	0.43
Hydrea				1					1	0.43
Fluconazole				1					1	0.43
Guaifenesin								1	1	0.43

Table 3 Continued

Drug Type	Clinical Features								TOTAL	%
	Urticaria	Angioedema	Erythroderma	Maculopapular	Fixed drug eruption	AGEP	DRESS	SJS/ TEN		
Chloroquine								1	1	0.43
Alprazolam				1					1	0.43
Procardio				1					1	0.43
Amiodarone				1					1	0.43
Simvastatin				1					1	0.43
PTU				1					1	0.43
NPTU				1					1	0.43
Ranitidine				1					1	0.43
Captopril				1				2	3	1.29
Methotrexate				1					1	0.43
Lansoprazole				1					1	0.43
Betahistine mesylate				1					1	0.43

Note: ATD = Anti-Tuberculosis Drugs; NSAID = Non-steroidal Anti-Inflammation Drugs; PTU = Propylthiouracil; NPTU = Non-Propylthiouracil

older people. Most of the patients with drug eruption were young, of the age group 20–39 years. This is in contrast to the research of Talib et al.[12] in Malaysia, which stated that men are more dominant in 69 subjects than women in 65 subjects, with an average age of 47 years.

Genetics and variability in the number of male and female patients in a hospital or polyclinic may be factors that can affect the prevalence of drug eruption patients.[13] Children are probably less frequent in having some allergic reactions, possibly owing to immaturity of the immune response and lower drug consumption. However, the prevalence in elderly patients increases up to 30%, being more severe, probably due to comorbidities and multiple consumption of medication.[14]

Other studies explained that several factors linked with growing age can contribute to an increase in the risk of ADRs, such as drug metabolism changes, frailty, multimorbidity, geriatric syndromes, cognitive and sensory impairment, and polypharmacy. Conditions affecting cognition are also crucial in terms of potential patient errors or noncompliance with treatment recommendations. Functional deficits and cognitive impairment, which are characterized by memory loss, decline in intellectual function, impaired judgment, and language, can have a practical impact on pill container management and decision-making skills. Older people frequently need many medications to treat multiple diseases. According to international figures, more than 60% of the elderly are taking five or more medications at the same time. The higher the number of drugs prescribed, the greater the risk of drug reactions and interactions.[15]

This study's most common clinical appearance of drug eruption was maculopapular in 90 people (45%). This was similar to the study of Janardhan et al.[16] in India, which mentioned that maculopapular was the most common clinical picture of drug eruption, with 171 cases out of 481 patients. The study of Patel et al.[17] in India stated the same: out of 3671 drug eruption patients, maculopapular was the most clinical picture in 1189 cases. In contrast to the study by Beniwal et al.[18], they reported that out of 200 patients, fixed drug eruption was the highest clinical picture in 82 cases. On the other hand, SJS/NET became the second most common clinical picture of drug eruption in this study, with 44 people (28%). Talib et al.[12] conducted a study with similar results.

Maculopapular has been identified as the most common clinical manifestation of an ADR. It can happen with almost any medicine. In fact, the majority of commonly used medications cause cutaneous reactions of more than 1%. Polypharmacy, immunosuppression, concurrent infection, systemic autoimmune illness, a high number of secondary conditions, and extreme age are all risk factors for maculopapular. The amount of concurrent medications a person takes raises their risk of maculopapular, which is most likely related to pharmacological and metabolic interactions. Maculopapular is becoming more common as prescription drug use and polypharmacy grow.[19]

The reasons for medication allergies vary greatly and differ depending on the time, location, and type of research presented. The frequency of drug use is closely related to the high prevalence of drug allergies.[20] In this study, the highest class of drugs that caused drug eruption was analgesics and non-steroidal anti-inflammatory drugs (NSAIDs), which were consumed alone or with other drugs (86 cases). The most common type of drug was paracetamol in 68 patients (29.18%). Then, antibiotic drugs (85 cases) were followed, with the most common type of drug being cotrimoxazole in 23 patients (9.87%). Analgesic and NSAIDs are commonly used and available without a prescription all over the world It became the most suspected causative eruption drug due to often used in the treatment of mild pain or fever to more severe symptoms, for example, in the treatment of rheumatoid arthritis.[21-23]

This study, in line with Jung et al.[24] reported that NSAIDs and acetaminophen were the main causative agents in drug eruption cases. It also aligns with Ben Fadhel et al.[25] that NSAIDs were involved in 51.2%, antibiotics in 24.4%, and other analgesics in 19.5%. But, in contrast with the study of Qayoom et al.[26] in India reported that from 75 patients, antibiotics were the leading cause of drug eruption, with quinolone being the most dominant in 28 cases. Ofloxacin was the most common drug in the quinolone group. Among the NSAIDs, piroxicam was the most commonly reported, while phenytoin was the most dominant in the anticonvulsant group.

Thus, the most clinical features of drug eruption in Dr. Hasan Sadikin General Hospital, Bandung is maculopapular and analgesics and NSAIDs drugs class, which is paracetamol, as the most suspected causative drug. There were several limitations in this study, such as the data used in this study came from secondary data, so there were some incomplete variable data, and

the causative drug data in this study were still suspicious. It also has no data about the diagnosis of each patient as the subject of this study, but it can be assumed that some drugs such as antibiotics, antiretrovirals, anticonvulsants, cardiovascular drugs, antithyroid, antifungal, antimalarial, chemotherapy were used as primary diagnostic treatment. On the other hand, the analgesics and NSAIDs group are the most often medications that caused the drug eruptions in this study and were assumed as drugs that were used both as primary and secondary diagnostic treatments. An oral provocation test, skin prick test, and other tests were needed for more accurate results about drug eruption.

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