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PRELIMINARY DATA OF 6  
MONTHS OBSERVATION

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## PROFILE OF DRUG HYPERSENSITIVITY PATIENTS HOSPITALIZED IN DR. SOETOMO HOSPITAL, SURABAYA, INDONESIA: PRELIMINARY DATA OF 6 MONTHS OBSERVATION

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### ABSTRACT

Drug hypersensitivity is defined as an untoward response to medication which is noxious and unintended, and which occurs at doses normally used in human either for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function. Drug hypersensitivity is common and may cause emergency condition until death. The incidence of drug hypersensitivity-related hospitalizations has usually been assessed within hospitals. The aim of this study is to determine the profile of drug hypersensitivity patients hospitalized at Dr. Soetomo Hospital in 6 months period from January to June 2016. This study was a descriptive retrospective study on medical records of drug hypersensitivity patients hospitalized in Dr. Soetomo Hospital in 6 months period. The patient's demographic data, the type of hypersensitivity reaction, and the final outcome of the hospitalization were collected. Within the 6 months period, there were 16 drug hypersensitivity patients hospitalized in Dr. Soetomo Hospital. Most of them are female (56.25%), and aged between 46-55 years (25%). There were 4 patients (25%) with type I hypersensitivity: urticaria, angioedema and anaphylaxis; while type IV hypersensitivity occurred in 12 patients (75%): Stevens-Johnson syndrome, Stevens-Johnson syndrome-Toxic Epidermal Necrolysis overlap, erythroderma, maculopapular drug eruptions, and DRESS. Most of the patients (87.5%) had favorable outcome after hospitalization. There were 16 patients with drug hypersensitivity reaction hospitalized in Dr. Soetomo Hospital, Surabaya in 6 months period. Most of them were female and had type IV hypersensitivity reactions.

**Keywords:** Drug allergy; treatment outcomes; type I hypersensitivity; type IV hypersensitivity

### ABSTRAK

Hipersensitivitas obat didefinisikan sebagai respons yang tidak diinginkan terhadap pengobatan yang berbahaya dan tidak diinginkan, dan yang terjadi pada dosis yang biasanya digunakan pada manusia baik untuk profilaksis, diagnosis, atau terapi penyakit atau untuk modifikasi fungsi fisiologis. Hipersensitivitas obat sering terjadi dan dapat menyebabkan kondisi darurat hingga kematian. Insiden rawat inap terkait hipersensitivitas obat biasanya telah dinilai di rumah sakit. Tujuan dari penelitian ini adalah untuk menentukan profil pasien hipersensitivitas obat yang dirawat di Rumah Sakit Umum Dr. Soetomo dalam periode 6 bulan dari Januari hingga Juni 2016. Penelitian ini adalah penelitian deskriptif retrospektif pada catatan medis pasien hipersensitivitas obat yang dirawat di rumah sakit di RSUD Dr. Soetomo dalam periode 6 bulan. Data demografi pasien, jenis reaksi hipersensitivitas, dan hasil akhir rawat inap dikumpulkan. Dalam periode 6 bulan, ada 16 pasien hipersensitivitas obat yang dirawat di RSUD Dr. Soetomo. Sebagian besar dari mereka adalah perempuan (56,25%), dan berusia antara 46-55 tahun (25%). Ada 4 pasien (25%) dengan hipersensitivitas tipe I: urtikaria, angioedema dan anafilaksis; sedangkan hipersensitivitas tipe IV terjadi pada 12 pasien (75%): sindrom Stevens-Johnson, sindrom Stevens-Johnson-Toxic Epidermal Necrolysis tumpang tindih, erythroderma, erupsi obat makulopapular, dan DRESS. Sebagian besar pasien (87,5%) memiliki hasil yang baik setelah rawat inap. Ada 16 pasien dengan reaksi hipersensitivitas obat yang dirawat di Rumah Sakit Umum Dr. Soetomo, Surabaya dalam periode 6 bulan. Kebanyakan dari mereka adalah perempuan dan memiliki reaksi hipersensitivitas tipe IV.

**Kata kunci:** Alergi obat; hasil pengobatan; hipersensitivitas tipe I; hipersensitivitas tipe IV

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## INTRODUCTION

The cases of drug hypersensitivity are increasing every year in various countries (Thong & Tan 2011). Meta-analyses have estimated that hospitalisations attributed to drug hypersensitivity account for between 2.4% and 6.4% of all hospital admissions in Western countries (Beijer & de Blaeij 2002). Many of them need emergency or intensive care and if not treated properly can be fatal, such as in the case of anaphylaxis or Stevens-Johnson syndrome (SJS) (Simons et al 2015). Some authors reported that in the United States, 36% of consultations were for evaluation of adverse drug reactions (ADRs) (England et al 2003). From January to December 2006, a total of 1412 outpatient paediatric and adult consults were requested of which 4.7% were for suspected drug allergy (Dietrich et al 2009). In Spain in 2005 there were 732 cases of suspected drug allergies with various symptoms and manifestations, 75% dermatitis, 0.75% SJS, and 10% anaphylaxis (Gamba 2009).

Adverse drug reactions is divided into 2 types, type A are predictable and type B unpredictable. The reactions that arising from medication errors, intentional overdoses, drug abuse, and medication administration errors are not included in the terminology of drug adverse reaction because their effects can be predicted (Solensky & Khan 2010, Riedl & Casillas 2003). Unpredictable drug reactions are the reactions that arise when administering drugs even as indicated and given in the right doses and method (Riedl & Casillas 2003).

Allergic reactions or drug hypersensitivity can occur through several mechanisms and can also manifest in several forms of abnormalities in some target organs and each type of abnormality requires its own treatment (Solensky & Khan 2010, Riedl & Casillas 2003).

Integrated data on various type of drug hypersensitivity in a hospital is very important to be used as a consideration for hospital management to improve the quality of medical services, to compile a list of drug needs, facilities and infrastructure needed and so on. The aim of this study is to determine the profile of drug hypersensitivity patients hospitalized in Dr. Soetomo General Hospital during period of January to June 2016.

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### MATERIALS AND METHODS

This study is a descriptive retrospective study on medical records of drug hypersensitivity patients hospitalized in all departments of Dr. Soetomo General Hospital, Surabaya during the above period. All medical

records that contain the diagnosis of drug allergy, drug reaction, drug hypersensitivity, or any clinical manifestation of type I or type IV drug hypersensitivity reactions were included. Any medical records with incomplete data or unclear description of drug involvement were excluded. Patient's demographic data, the clinical manifestations, and the outcome of hospitalization we collected and recorded.

Drug allergy or hypersensitivity were diagnosed based on signs and clinical symptoms from patient. Data from physical examinations were mostly sufficient to establish the clinical diagnosis. Some clinical diagnosis need additional supporting laboratory examination such as eosinophil count and the level of liver enzymes for DRESS, or skin biopsy.

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This study was approved by the Health Research Ethics Committee of Dr. Soetomo General Hospital, Surabaya, Indonesia with certificate number of 746/Panke.KKE/XII/2017.

## RESULTS

There were 16 patients diagnosed as having drug hypersensitivity during the study period. Most of them were female (56.25%), aged between 46-55 years (25%). The type IV drug hypersensitivity reactions were more common than the type I reactions. Most of the patients (87.5%) had favorable outcome (recovered or getting better) after hospitalization. Table 1 summarize the collected data.

## DISCUSSION

This study is a preliminary report of drug hypersensitivity patient's data hospitalized in Dr. Soetomo General Hospital, Surabaya. In order to know the real burden of the disease, to compile a list of drug needs, facilities and infrastructure needed, and so on, we only starting to analyzed all the data of hospitalized patients. We can only rely on the written diagnosis of drug hypersensitivity by the attending physicians on the medical records discharge summary. Our results were more or less similar to other finding in Indonesia. Darmani et al (2014) stated that only 7 patients (20%) of had type I hypersensitivity (urticaria) from a total of 35 patients with drug allergy (Darmani et al 2016). This findings is similar to our study that type I was less than type IV hypersensitivity. Thong and Tan's study (2011) also reported that 67% of hospitalized allergic patients had type IV hypersensitivity such as exanthema, erythroderma and SJS/TEN (Thong & Tan 2011).

Table 1. Profile of drug hypersensitivity patients hospitalized in Dr. Soetomo General Hospital, Surabaya from January to June 2016

Characteristics	Frequency n=16	Percentage
Type of hypersensitivity		
Type I	4	25.00 %
Urticaria / angioedema	2	
Anaphylaxis	2	
Type IV	12	75.00 %
SJS	3	
SJS/TEN Overlap	1	
Erythroderma	4	
DRESS syndrome	3	
Maculopapular drug eruption	1	
Sex		
Male	7	43.75 %
Female	9	56.25 %
Age group		
0-5 years	1	6.25 %
12-16 years	2	12.50 %
17-25 years	1	6.25 %
26-35 years	2	12.50 %
36-45 years	2	12.50 %
46-55 years	4	25.00 %
56-65 years	2	12.50 %
> 65 years	2	12.50 %
Outcome		
Recovered	5	31.25 %
Getting better	9	56.25 %
Patient's self forced discharge	2	12.50 %

Note: DRESS: Drug Reaction with Eosinophilia and Systemic Symptoms; SJS: Stevens-Johnson syndrome;  
 TEN: toxic epidermal necrolysis

In Gamboa's study (2009) according to Allergologica 2005 survey, the drug allergies were more common in female compared to male (62% versus 38% respectively, F/M ratio of 2:1) (Gamboa 2009). Darmani et al (2016) also reported that female outnumbered male counterpart by 60% to 40%. Thong et al (2003) showed that drug allergic patients in female were 119 patients (56.7%) and male were 91 patients (43.3%) (Thong et al 2003). In this study, female cases were also more frequent (56.25%) compared to the male (43.75%). These findings can be explained partly by different cytochrome P3A4 activity that affects the metabolism and synthesis of drug metabolites and hence the action of drugs in the body (Anderson 2008). In female, the CYP3A4 is more active compared to male. So, female can also be more vulnerable to experience hypersensitivity reactions to drugs (Shakya et al 2004).

In the study of Darmani et al (2016) the most common age group was the 41-50 years group (25.7%). That study was also conducted in Indonesia. Somewhat similar to theirs, our study also found that the drug hypersensitivity was most prevalent in the 46-55 year age group (25%). It is understandable that the older the person, the more he or she will suffered from any

disease, especially the degenerative diseases. Older persons usually consume more drugs for their medication compared to the young, hence they will have a higher probability of drug hypersensitivity (Mihardja & Soetrisno 2012).

In Mexico's research in 2006 there were 6 patients (16.6%) who died (Thong & Tan 2011). Thong et al (2011) described the mortality rate in SJS, SJS/TEN overlap, and TEN was 10%, 30%, and 50%, respectively (Thong & Tan 2011). Cho et al (2017) also reported that the death rate in DRESS patients were reaching 10% (Cho et al 2017). In our study, of 16 patients, 5 were recovered while the other 9 were getting better, giving the favorable outcome of this observational study. There was no death case recorded during our study period. Considering the short period of our observation, we need to collect more data to see the outcome of more severe drug hypersensitivity patients. Patients with severe cutaneous adverse drug reactions (SJS, TEN, DRESS, and erythroderma) are more susceptible to complications such as sepsis and fatal outcomes because the skin barrier is damaged and microorganism can easily enter the body's circulation (Sasidharanpillai et al 2015).

## CONCLUSION

During the period of 6 months observation from January to June 2016, there were 16 patients with drug hypersensitivity reaction hospitalized in Dr. Soetomo General Hospital, Surabaya. Most of them were female and had type IV hypersensitivity reactions. The most common age group was the 46-55 year group. The majority of patients had favorable outcome after treatment in the hospital.

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