

# A Preliminary Study of Adverse Drug Reactions in a Tertiary Care Hospital of Kashmir

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## ABSTRACT

**Purpose:** To study the adverse drug reactions (ADR's) reported from Dermatology ward in SMHS hospital of Srinagar. The adverse drug reactions were analyzed by Naranjo's causality assessment scale and the outcomes were studied.

**Methods:** This observational and cross-sectional study was conducted for one month of July 2018 in an inpatient setting of Dermatology ward of SMHS hospital. The data collection was done only in Dermatology ward. Patients of all age groups and either sex were included in this study. The adverse drug reactions were assessed for their causality by performing the Naranjo's algorithm scale. The outcomes were studied.

**Result:** Total 3 adverse drug reactions were reported from Dermatology ward. 20-40 years age group was studied for adverse drug reactions. The most commonly affected organ is the Skin 2 (66.66%), followed by Reproductive system 1 (33.34%). The 3 reported ADR's were Acute Urticaria in 2 patients and Azoospermia in 1 patient. According to Naranjo's algorithm scale, out of 3 suspected ADR's 2 (Azoospermia: Cyclophosphamide and Acute Urticaria: Sulfasalazine) were probable and 1 suspected ADR (Acute Urticaria: Tetanus Toxoid) was possible. Out of 3 patients, 2 with Acute Urticaria recovered while as patient with Azoospermia continued with the problem during study.

**Limitations:** Study was conducted only in one ward i.e., Dermatology and patient number was also less.

**Keywords:** adverse drug reactions, Acute Urticaria, Jammu

## INTRODUCTION

Drugs are intended to use for diagnosis, prevention, treatment and as prophylaxis of various diseases. But it is sometimes observed, that these drugs also show some adverse effects. This could be due to variable person-to-person response towards a drug. Even at therapeutic doses, people develop adverse effects. Adverse effects have been classified in many ways. One may classify them into two categories: predictable (Type A or Augmented) reactions and Unpredictable (Type B or Bizarre) reactions.

World health organization (WHO) defines an adverse drug reaction (ADR) as a response to a drug which is noxious and unintended and which occurs at doses normally used for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function". According to epidemiological studies,

ADR's account to 3.4% of hospital admissions and 1.8% mortality in India (**Charu Bahri, 2016**).

It is the 4<sup>th</sup> leading cause of death all over world (**Lazarou J, 1998**). ADR's are a leading cause of morbidity and mortality in many countries. It is a great concern for public, medical professionals, pharmaceutical industry, regulatory authorities and other health care professionals. India is a country which has supported the WHO program for global monitoring of ADR's that is done by spontaneous reporting, because of this reporting system, many drugs were banned in the market for the safety reasons. Government of India launched the pharmacovigilance programme of India (PVPI) in 2010, its main function is to monitor adverse drug reactions by establishing Adverse Drug Reactions

Monitoring Centers (AMC) across India. Currently there are 170 AMC in India (**Singh KNM, 2017**).

#### REVIEW OF LITERATURE

Effect of cyclophosphamide on spermatozoa is well documented (**Jianping Qiu et al 1992**), who reported that cyclophosphamide may have an adverse effect on spermatozoa. A study was also conducted on the use of Testosterone to prevent Cyclophosphamide induced Azoospermia. They reported that continuous use of Cyclophosphamide for 6-8 months induces Azoospermia (infertility) (**Masala, et al 1997**).

In another conducted study on Drug induced urticaria where it was reported that Drug induced Urticaria is most commonly caused by Penicillins, Sulfonamides and NSAIDs (**Shipley D, et al., 2001**).

Adverse Reactions To Tetanus Toxoid and it is reported there that Urticaria is one of ADR's of Tetnus toxoid (**WG White et al.1973**)

Immediate Allergic Reactions after administration of Tetanus toxoid on 4 children. The study showed that children developed urticaria as an ADR (**Myorga C, et al. 2003**).

#### OBJECTIVE:

To study the adverse drug reactions (ADR's) reported from Dermatology ward in SMHS hospital of Srinagar.

To bring awareness regarding adverse reactions of various drugs.

#### METHODOLOGY

This observational and cross-sectional study was conducted for 1 month (July 2018) in an inpatient setting of dermatology ward of SMHS hospital in Srinagar Kashmir. The data collection was done only in one ward. Patients of all age groups and either sex were included in this study. The Adverse drug reaction form filled by health care professionals was considered. The adverse drug reactions were assessed for their causality by performing the

Naranjo's algorithm scale. The outcomes were studied.

Exclusion criteria: OPD patients are excluded. The use of alternative system of medicines such as Ayurveda, Homeopathy, Unani etc, excess consumption, was excluded. Patients who are mentally retarded, drug addicted, suicidal tendencies or consumption of a drug in the influence of alcohol was also excluded.

#### RESULTS AND DISCUSSION

In this study only 3 patients were reported to experience an ADR. Total 3 adverse drug reactions were reported from Dermatology ward. 20-40 years age group was studied for adverse drug reactions. The most commonly affected organ is the Skin 2 (66.66%), followed by Reproductive system 1 (33.34%). The 3 reported ADR's were acute Urticaria in 2 patients and Azoospermia in 1 patient. According to Naranjo's algorithm scale, out of 3 suspected ADR's 2 (Azoospermia: Cyclophosphamide and Acute Urticaria: Sulfasalazine) were probable and 1 suspected ADR (acute Urticaria: Tetanus Toxoid) was possible. Out of 3 patients, 2 with Acute Urticaria recovered while as patient with Azoospermia continued with the problem during study (Table 1 & 2).

CASE 1. A 20 year old female patient who received Tetanus Toxoid and experienced Acute Urticaria .Tetanus Toxoid was prescribed to the patient for the treatment of forehead injury. Therapy began on 23<sup>rd</sup> July 2018 and was withdrawn on the same date.

CASE 2. A 30 year old male patient who received cyclophosphamide and experienced Azoospermia. Cylophosphamide was prescribed to the patient for the treatment of Pemphigus vulgaris. Therapy began on 10 October 2016 and was withdrawn on 7<sup>th</sup> DCP cycle of therapy 27 September 2017.

CASE 3. A 36 year old female patient who received Sulfasalazine and experienced Acute Urticaria. Sulfasalazine was prescribed to the patient for the treatment of Arthritis. Therapy began on 18 June 2018 and was withdrawn on 24 July 2018.

**Table-1:** Details of ADR

S. No	ADR	Suspected Drug	Route of Administration	Organ System Affected	Dose	Dosage Regimen	Drug Indication	ADR Causality Assessment	ADR Labeled	Action Taken for ADR	Treatment To ADR
1.	Acute Urticaria	Tetanus Toxoid	Intra-muscular	Skin	0.5 mL	0.5 mL once only	Skeletal Injury	Possible	No	No Action Taken	Medical Treatment
2.	Azoospermia	Cyclophosphamide	Intravenous Drip	Reproductive System	500 mg	500 mg once a day	Pemphigus vulgaris	Probable	Yes	Drug withdrawal	Medical Treatment
3.	Acute Urticaria	Sulfasalazine	Oral	Skin	1000 mg	1000 per day	Arthritis	Probable	Yes	Drug withdrawal	Medical Treatment

**Table-2:** Patient details

S. No.	ADR	Patient's Age	Sex	Concomitant Medication	Relevant Medical History
1.	Acute Urticaria : Tetanus Toxoid	20 years	Female	No	History of Tetanus Toxoid Injection 3 times from last 3 months
2.	Azoospermia : Cyclophosphamide	30 years	Male	Dexamethasone, Calcium Citrate Malate	Patient a known case of Pemphigus vulgaris from last 3 years
3.	Acute Urticaria : Sulfasalazine	36 years	Female	Methylprednisolone	No relevant medical history available

## CONCLUSION

Adverse drug reaction is an undesirable or unintended consequence of drug administration. It is a broad term, includes all kinds of noxious effects-trivial, serious or even fatal. The main aim of studying adverse drug reactions is to establish a system of rational use of drugs. In this study few cases of ADR were considered from inpatients of dermatology ward. After an ADR, the drug was withdrawn and re-challenge was not performed in any patient. In order to make safety and rational use of drugs there is need of more concern from health care professionals towards ADRs and their reporting.

**Acknowledgement:** The authors would like to acknowledge Dr. Sameena Farhat (Head, Department of Pharmacology) and Dr. Zubair Aishae (Department of Pharmacology) for giving an opportunity to conduct this study in Shri Maharaja Hari Singh (SMHS) Hospital, Srinagar, J&K, India

**Conflict of Interest:** None

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