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A case study on adverse drug reactions (ADR'S) monitoring in dermatology patients centre of tertiary care S. V. S. Medical College & Hospital

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ABSTARACT

The observational and brief cross section study was conducted in the ADR monitoring centre, department of pharmacology, SVS MEDICAL HOSPITAL. The adverse drug reactions (ADR) reported by physician of dermatology department of SVSMH were collected and then causality, severity and preventability assessment was done. The results were presented as number and percentage. Total of 544 patients were observed with 74 suspected ADRs. The incidence of dermatological ADR was 3.78%. Most commonly manifested ADR was rash (26.67%). Total 97 drugs were suspected. Maximum incidence of dermatological ADRs were observed with anti-inflammatory agents and immunosuppressive (33.30%) followed by antibiotic drugs (13.3%).Dermatological adverse drug reactions were a common occurrence and awareness about them was found to be essential for early detection and prevention. The healthcare system can promote the spontaneous reporting of dermatological ADR top Pharmacovigilance centre's for ensuring safe drug use and patient care. . Most of the reported ADRs were possible, definitely preventable and mild in nature. Our study suggests that there is a need of intensive monitoring for ADRs in tertiary care hospital for early detection and to ensure the patient safety.

Keywords: adverse drug reaction, casuality, severity, probability.

INTRODUCTION

Adverse drug reactions are defined as any noxious unintended and undesired effects of a drug that occur at doses used for prevention, diagnosis or treatment[1]. An adverse drug reaction (abbreviated ADR) is an expression that describes harm associated with the use of given medications at a normal dosage during normal use [1]. ADRs may occur following a single dose or prolonged administration of a drug or result from the combination of two or more drugs. The meaning of this expression differs from the meaning of "side effect", as this last expression might also imply that the effects can be beneficial [2] The study of ADRs is the concern of the field known as pharmacovigilance. An adverse drug event (abbreviated ADE) refers to any injury caused by the drug (at normal dosage and/or due to overdose) and any harm associated with the use of the drug (e.g. discontinuation of drug therapy)[3]. ADRs are a special type of ADEs.

In everyday clinical practice, almost all physicians come across many instances of suspected adverse cutaneous drug reactions (ACDR) in different forms. Although such cutaneous reactions are common, comprehensive information regarding their incidence, severity and ultimate health effects are often not available as many cases go unreported.

In the present world, almost everyday a new drug enters market; therefore, a chance of a new drug reaction manifesting somewhere on some form in any corner of world is unknown on unreported. Although many a times ,presentation is too trivial and benign, the early identification of the condition and identifying the culprit drug and omit it at earliest holds the keystone in management and prevention of a more severe drug rash. Therefore, not only

the dermatologists, but all practicing physicians should be familiar with these conditions to diagnose them early and to be prepared to handle them adequately. Combined use of multiple drugs may cause adverse events. Drug interactions can lead to an increase or a decrease of the drug effects or cause other serious reactions. For example, co administration of a drug metabolized by Cytochrome P450 3A4 (CYP3A4) and the drug inhibiting CYP3A4, such as cyclosporine and clarithromycin, respectively, result in delayed clearance and elevated blood levels of the former drug, which increases and prolongs both the therapeutic and adverse effects [4]. A common misconception is that a drug's effects can be clearly divided into two categories: desired(or therapeutic effects) and undesired (or side effects).Actually ,most drugs produce several effects ,but a physician usually wants a experience only one (or a few) of them; the other effects are hence regarded as undesired. Although most people including healthcare practitioners use the term *'side effect'*, the term *'adverse drug reaction'* is more appropriate for effects that are undesired, unpleasant, noxious or potentially harmful.

➢ Although many of the ADR's are relatively mild and disappear when the drug is stopped or the dose is reduced, others are more serious and long laster. Therefore. There is little doubt that ADR's increase not only morbidity and mortality, but also add to the overall healthcare cost[7,8].

Some ADR's are predictable in nature especially those where a contraindicated drug is used (in patient with a known allergy or with co-morbidities contraindicating its use) or the wrong dose of a drug administered. The importance of understanding the predictability of an ADR was first reviewed in 1971. Where it was estimated that 70-80% of ADR's are predictable and may be preventable .It is true that some ADR's are unavoidable and will occur even with the most extraordinary precautions in place. However, a large proportion of ADR's may be preventable. Yet, in most hospitals today, too little is done to identify and understand preventable ADR's. This information is of utmost importance for guiding educational programs and systems to facilitate a reduction in the number of ADR's that occur. The [preventability of ADR's is an appropriate data element which can be fed back into the system to facilitate the improvement process.

IMPORTANCE OF ADR REPORTING IN INDIA:

Adverse Drug Reactions are fourth to sixth leading cause of death among hospitalized patients and it occurs in 0.3 per cent to 7 per cent of all hospital admissions. The incidence of serious ADR's is 6.7 percent [5]. There is a rapid increase in the number of new drugs entering the market from last few decades India being the second most populated country has over one billion potential drug consumers, and no amount of pre-clinical and clinical data is sufficient to conclude the complete safety of a drug, under this scenario it becomes necessary to report any untoward reaction of any pharmaceutical product to assess its safety and efficacy to ensure maximal patient health.

MATERIALS AND METHODS

STUDY LOCATION:

The study will be carried out in the S.V.S Medical college & Hospital including both outpatient and inpatient departments.

STUDY DESIGN:

The study will be an observational type, prospective and descriptive type.

STUDY PERIOD:

Study period will be of 6 months (november 2014 to march 2015).

STUDY SETTING:

Study will be based only on those patients who experience an adverse reaction to medicine used either during their stay in hospital (IPD) or visiting the outpatient departments (OPD) of dermatology.

STUDY CRITERIA:

Inclusions:

➢ Patient's name, age, gender.
➢ Drug Prescribed.
➢ Dosage of Drugs Prescribed & dosage form.
➢ Route of Administration.

Exclusions:

➢ Incomplete information regarding patient.

DATA COLLECTION:
Data on the Reported ADRs will be evaluated to understand the pattern of the ADRs with respect to patient demographic disease, Nature of the reactions, characteristics of the drugs involved, and outcome of the reactions.

Criteria for identifying ADRs:
ADR identified by physicians will be considered and will be included in the study.

ANALYSIS OF ADRs:

The total number of ADRs reported.

Nature and description of ADDRs reported.

Causality assessment of ADR based on Algorithm [9, 10].
The degree of association of an adverse of an adverse reaction with a drug is done with the help of Naranjo's algorithm.

Severity of ADRs :
After the causality assessment has been done, the severity of the ADR is analyzes using adapted Hart wig severity scale.

The Scale is classified as:
1. **Mild:** A reaction that does not required treatment or hospital stay.
2. **Moderate:** A reaction that requires treatment and or prolongs hospitalization by at least one day**.**
3. **Severe:** A reaction that is potentially life threatening or contributes to the death of patient is permanently disabling requires intensive medical care or results in a congenital anomaly cancer or unintentional overdose.

To study the onset of ADRs:
1. Acute: Acute events are those which are observed within 60 minutes after the administration of medication.
2. Sub-Acute: These occur within 1-24 hours from the time f administration of medication.
3. Latent: These reaction take 2 more days to become apparent.

Preventability of ADRs:
Complete preventability of ADR is not possible, but some of the ADR can be preventable if that ADR can give at least one answer of Schumock and Thornton Scale.

Predictability of ADRs:
Patients who have had the drug on previous occasion(s): If the drug was previously well-tolerated at the same dose and route of administration, the ADR is NOT PREDICTABLE; there was a history of allergy or previous reaction to the drug, the ADR is PREDICTABLE. Patients who have never had the drug previously: Incidence of the ADR reported in product information or other literature determines its predictability.

STATISTICAL ANALYSIS:
- All the data collected during the study will be processed using SPSS software.
- All the data will be represented as average (±SEM) and percentages,
- Rates of ADR or ADR occurrence during the hospital stay will be calculated as percentage of in-patient or out-patient population treated.
- Student's t-test will be use to compare mean values.

RESULTS AND DISCURSION

Assessment of ADR according to gender:

Female number of patients:	250
Male number of patients:	294
Total number of patients:	544
Female number of ADRs:	04
Male number of ADRs:	11
Total number of ADRs:	15

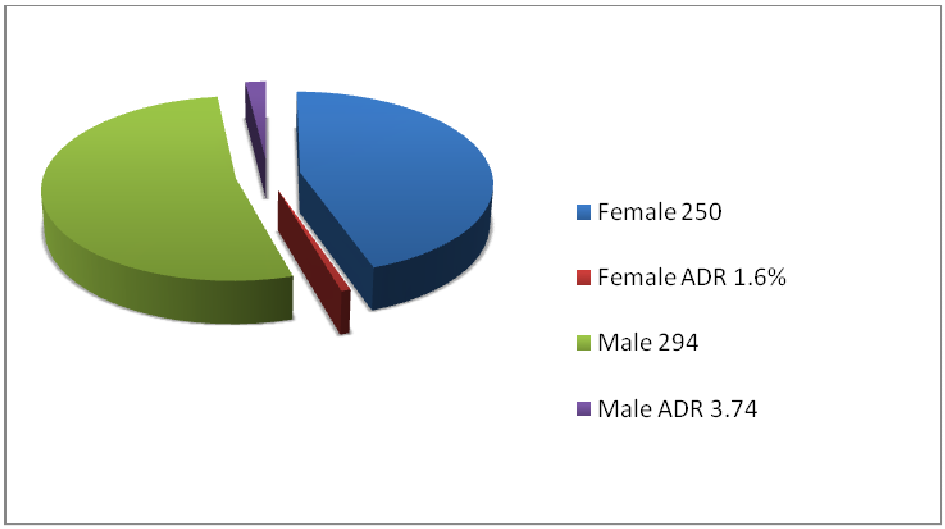

Figure 1 . graphical representation of ADR according to gender

Table 1. Age distribution of the patients among male and female

Frequency	Male	Female	No. ADR	Percentage
0 – 10	24	17	03	7.3%
11 – 20	69	56	04	3.2%
21 – 30	94	92	05	2.6%
31 – 40	43	46	02	2.2%
41 – 50	25	52	00	0%
51 – 60	16	10	00	0%
61 – 70	19	03	01	4.5%
71 – 80	04	01	00	0%

Table 2.Pharmacological class Vs number of ADRs in patients:

Pharmacological class	Number of patients	Percentage of patients
NSAIDs	02	13.3%
Local anesthetic agent	02	13.3%
Anti-inflammatory and immunosuppressive	05	33.3%
Anti-biotic	02	13.3%
Anti-convulsant	01	6.6%
Anti-cancer	01	6.6%
Ayurvedic medicine	01	6.6%
Anti-fungal	01	6.6%

Table 3.Casualty assessment

Casualty	Number of patients	Male	Female
Definite	07	05	02
Probable	07	05	02
Possible	01	00	01
Unlikely	00	00	00

Table 4.Severity of ADR distribution:

Severity	Number of patients	Male	Female
Mild	11	8	3
Moderate	2	1	1
Severe	2	2	0
Fatal	0	0	0

Table 5 .the particular relating to cutaneous ADRs

S.No	Age	Gender	Drug name	Route of administration	Category	Type of ADR	Dose	Category severity
1.	08	M	Ofloxacin	Oral	anti-biotic	Type A- Dose dependent	200 mg	Sever Level-5
2.	14	F	metronidazole	Oral	anti-biotic	Type A- Dose dependent	200 mg	Moderate Level-4
3.	70	M	Clorambucil	Oral	Anti-cancer	Type-B-Idiosyncratic	2 mg	Severe Level-5
4.	33	F	Diclofinac sodium	Oral	NSAIDs	Type-B-Idiosyncratic	50 mg	Mild Level-2
5.	30	M	Lignocaine	Cutaneous	Local anesthetic	Type-H hyper sensitivity	½ cc (30% v/v)	Mild Level-2
6.	27	M	Lignocaine	Cutaneous	Local anesthetic	Type-H hyper sensitivity	½ cc (30% v/v)	Mild Level-2
7.	25	F	Ayurvadic medicine	Oral	-	Type-F – therapy failure	-	Mild Level-2
8.	28	M	Clobetasol propionate	Topical	Anti-inflammatory & immunosuppressive	Type-B-Idiosyncratic	0.05%	Moderate Level-4
9.	36	M	Clotrimazole	Topical	Antifungal	Type-B-Idiosyncratic	5 gm (0.5 w/w)	Mild Level-2
10.	10	F	Betamethasone dipropionate	Topical	Anti-inflammatory & immunosuppressive	Type-H hyper sensitivity	20gm (0.05%w/w)	Mild Level-2
11.	16	M	Betamethasone dipropionate	Topical	Anti-inflammatory & immunosuppressive	Type-H hyper sensitivity	20 gm (0.2%w/w)	Mild Level-2
12.	20	M	Beclomethasone	Topical	Anti-inflammatory & immunosuppressive	Type-F – therapy failure	5gm (0.025%w/w)	Mild Level-2
13.	19	M	Betamethasone volerate	Topical	Anti-inflammatory & immunosuppressive	Type-B-Idiosyncratic	20gms (0.01%)	Mild Level-2
14.	06	M	Sodium valproate	Oral	Anti-conversant	Type-B-Idiosyncratic	100ml (200mg)	Mild Level-2
15.	28	M	Diclofinac sodium	Oral	NSAIDs	Type-H hyper sensitivity	150mg	Mild Level-2

CONCLUSION

ADRs are potentially avoidable causes for seeking medical attention. They increase the burden of work and can be fatal at times adding to the common person's negative perception of allopathy. With the number of drugs being marketed increasing every year, it is of paramount importance to have an in-depth knowledge of their possible adverse reactions and this is possible only when the physician is trained adequately and have knowledge on incidence of various adverse drug reactions. There are variations in the results in comparison to other studies like female predominance, offending drugs like among antimicrobials were found to be commonly involved. Among different medications anti-inflammatory group and antibiotics were commonly responsible drugs. Causality assessment also resulted in high score of definite category. A robust mechanism for reporting of ADRs is required while the clinician is to be always on the lookout for ADRs. So, anticipating, preventing, recognizing and responding to ADRs should be the prime concern of the clinicians so as to minimize the incidence of ADRs.

Results of this study emphasized the need of ADR reporting in tertiary care hospitals to help in assessing the benefit risk ratio of drugs. From this study, it had been concluded that incidence of CADRs occurrence was high in female patients.

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