Print ISSN: 2319-2003 | Online ISSN: 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20171673

Original Research Article

A study on incidence of adverse drug reactions with commonly prescribed drugs and causality assessment in Silchar Medical College and Hospital

Jahirul Islam Laskar*, Pinaki Chakravarty, Babul Dewan

Department of Pharmacology, Silchar Medical College and Hospital, Silchar, Assam, India

Received: 08 March 2017
Accepted: 01 April 2017

***Correspondence to:**
Dr. Jahirul Islam Laskar,
Email: dr.jahirul@gmail.com

ABSTRACT

Background: Present study was carried out to assess the incidence of adverse drug reactions (ADRs) and assessment of causality, severity with reported suspected ADRs.
Methods: A prospective observational study was conducted over a period of one year in inpatients and out patients hospitalization due to ADRs, at Silchar Medical College & Hospital, Silchar, Assam. WHO–UMC Probability scale was used for causality assessment. Reported ADRs were classified according to Wills and Brown classification and assessed for severity using scale developed by Hartwig et al. All data were calculated by 'Descriptive statistics' analysis as percentage of patient population who encountered ADRs.
Results: A total of 192 suspected ADRs were reported and Overall incidence of ADRs during the study period was found to be 0.41% of which 0.22% of ADRs had lead to hospital admissions and 0.19% of ADRs occurred during the hospital stay. Most common drug class associated with ADRs were Antimicrobials [101(52.6%)], which was found to have mostly affected the Skin system followed by NSAIDs [24(13.54%)], Haematinics [21(10.93%)]. Severity of the ADRs were found to be moderate [79(41.14%)], followed by [71 (36.97%)] ADRs which were severe and [42(21.87%)] which were mild.
Conclusions: Present study revealed that, more awareness about the importance of Pharmacovigilance have to be provided among the health care professionals by way of ADR bulletins, seminars and workshops. Also, more studies need to be conducted in Indian population to know the exact prevalence of ADRs in Indian hospitals.

Keywords: Adverse drug reaction, Causality assessment, Severity, Spontaneous reporting

INTRODUCTION

An adverse drug reaction (ADR) is defined by the World Health Organization (WHO) as any noxious, unintended, or undesired effect of a drug that occurs at doses used in humans for prophylaxis, diagnosis, or therapy.[1] ADRs are a major cause of morbidity and place a substantial burden on limited healthcare resources.[2] Multiple factors influence ADR susceptibility, including multiple drug therapy, disease severity, age, and the type and number of drugs prescribed.[3]

Adverse drug reactions (ADRs) are global problems of major concern.[5] They affect both children and adults with varying magnitudes, causing both morbidity and mortality.[7] In addition to the human costs, ADRs have a major impact on public health by imposing a considerable economic burden on the society and the already stretched health-care systems.[8] Post marketing surveillance of drugs is very important in analyzing and managing the risks associated with drugs once they are available for the use of the general population.[9]

Most of the advanced countries have set up an ADR reporting system at the national level. ADR reporting programs on an institutional basis can provide valuable information about potential problems in drug usage in that institution. Furthermore, reviewing pooled data from diverse geographic, social and medical population enhances the ability to identify rare events and to generate new signals and thus in setting up a sound Pharmacovigilance system in the country.[10]

ADR in hospital patients are divided into two categories: those that cause admission to hospital and those that occur in hospital inpatients after admission. Hospital based ADR monitoring can provide valuable information on drug usage.[11] ADR add an unnecessary cost to an already burdened health care system and are usually preventable.[12]

In India, the concept of ADR reporting is still new although ADRs are of great concern to the general public, medical practitioners, pharmaceutical industries and the regulatory authorities.[13] We have very few ADR monitoring centers right now and a lot of effort is required to collect ADR related data which may be helpful to generate safety surveillance of billions of therapeutically active substances, either alone or in combinations.

The present research works was carried out in Silchar Medical College and Hospital, Silchar which is 1023 bedded multispecialty tertiary care teaching hospital providing healthcare services to the people in and around Silchar city, Cachar District of Assam. The objective of this research to find out the incidence and the pattern of ADRs occurring in this hospital, to assess the causality, to identify the offending drugs, to establish a causal relationship with the suspected drug. The study will be first of its kind in this hospital.

METHODS

This is a hospital based study conducted in the Silchar Medical College and Hospital which is a 1023 bedded tertiary care hospital, the only referral hospital located in the southern part of Assam. It is the sole custodian of health care system of the entire Barak Valley. All patients above 18 years of age, who were admitted to the hospital due to ADRs and all in patients with suspected ADRs during their hospital stay were enrolled for the study. This is a non-interventional, prospective, observational study, conducted at Silchar Medical College and hospital for a period of one year.

The consent form and the patient information sheet were provided in a vernacular language (English, Hindi and Bengali) to the patients or legally acceptable representative (LAR). The same consent form was used in the individual patient /LAR after explaining the detailed purpose of the study. The patients were recruited only after they signed the consent form willingly and satisfying the Inclusion and Exclusion criteria's for the study

Inclusion criteria

- Patients of either sex above 18 years of age
- Patients admitted to Hospital due to suspected ADRs.
- Hospitalized patients who developed ADRs.

Exclusion criteria

- Suspected ADRs patients who are not willing to give informed consent.
- Patients with intentional or accidental poisoning.
- Patients who developed an ADR during transfusion of blood or blood products and vaccines/any material.
- Patients treated on Outpatient department (OPD) basis.
- Patients with drug abuse and patients with non-compliance.

Data collection

WHO definition of an ADRs was adopted. Spontaneous reporting system method was followed for monitoring ADRs. Medical staff, medical post graduates, nursing staff and patients were encouraged and sensitised to report ADRs by creating awareness through brief presentations and conducting clinical meetings with the help of adverse drug reaction monitoring centre of this hospital. ADR notification forms were kept in the nursing stations of all the departments in the hospital.

Adverse drug reaction monitoring centre played a crucial role in monitoring, through participation in the ward rounds at regular basis and encouraging the physicians to report the ADRs. Any reaction noted by the healthcare professionals were brought into the notice of the concerned physician. The physician if convinced enough of the ADR would fill the ADR notification form and inform the ADR monitoring centre, who would take further action to collect the ICSR. Informed consent was taken from the patients for suspected ADR before their documentations. The demographic details of the patients were collected. The drug therapy details were recorded in a systematic manner in a pre-designed patient profile form. All relevant data including the drugs, patient had received prior to the onset of the reaction, their doses, and the route of administration with frequency, date and time of the onset of reactions were recorded. A detailed history of allergy to any known or unknown substance was also noted. In addition to this, patient's medication history other co-morbid conditions were identified to assess causality relationship between the suspected drug and the reaction. Patients were interviewed and the medication order and records were reviewed on regular basis throughout the patient's stay in the hospital. Any drug treatment and/or supportive therapy given for management of the reactions were noted. Clinical staffs were sensitized by a leaflet issued from the Department of Pharmacology Regional Resource Centre for Training and Technical Support (RRCTT) to inform any suspected ADR cases to the ADR monitoring centre SMCH, by notification cards that were already available in the nursing

stations of the various departments in the hospital. The phone number and mail id of the Pharmacovigilance associate and mine were widely circulated through the leaflet for everyone to communicate any suspected ADR cases to our centre. After receiving the information regarding any suspected case of ADR, investigators would go to the individual ward to ensure that all detected, undetected and suspected details regarding the ADRs were collected.

The patient and his accompanying associates were briefed about the visit and purpose of collecting the information who in turn, if gave consent to participate in the study were further evaluated. All the details of the suspected ADRs were collected and recorded in the ADR monitoring form and proforma used for this study. The ICSR was reported to the Pharmacovigilance associate of PvPI for onward transmission through Vigiflow for central assessment at IPC, Ghaziabad. Individual patients were followed up regularly during their hospital stay till the final outcome. Various parameters related to collect ADRs were assessed using different tools.

Causality assessment by WHO–UMC standardized case causality assessment criteria

The causal relationship between the suspected drug and the reaction was established by using WHO–UMC standardized case causality assessment criteria. The causality of reported reactions were categorized into any one of the following categories: i.e certain, probable, possible, un-assessable/unclassifiable, unlikely, conditional/unclassified using the WHO causality assessment scale.[14]

ADRs classification according to Wills and Brown classification

The reported suspected ADRs were classified according to the Wills and Brown classification.[15] Adverse reactions are classified into nine categories based on their mechanism. In this classification, the term medicine has been used in preference to drug to ensure that reactions secondary to the method of administration or excipients are clearly incorporated within the definition.

Assessment of severity was graded as per Hartwig's severity scale

According to FDA, a serious reaction is classified as one which is fatal, life threatening, prolonging hospitalization, and causing a significant persistent disability, resulting in a congenital anomaly and requiring intervention to prevent permanent damage or resulting in death, Hartwig SC, Seigel J and Schneider PJ categorised ADRs into seven levels as per their severity. Level 1 and 2 fall under mild category whereas level 3 and 4 under moderate category and level 5, 6 and 7 fall under severe category. Severity of ADR was graded as per scale developed by Hartwig et al.[16]

Statistical analysis

The demographic details of the patients and the Incidence of ADRs related admissions and ADRs reported during the hospital stay were calculated by descriptive statistics analysis as percentage of patient population who encountered ADRs.

RESULTS

Table 1: No. of adverse drug reactions.

Reactions	Reactions(no.)	%
Abdominal pain and headache	1	0.52
Skin rashes	24*	12.5
Anaemia	3	1.56
Anaphylactic shock	19	9.89
Asthenia	1	0.52
Blurred vision	1	0.52
Breathing difficulty	1	0.52
Cutaneous vasculitis	1	0.52
Diarrhoea	1	0.52
Drug eruption	9	4.68
Edema	1	0.52
EPS	15	7.81
Erythema	18	9.37
FDE	14	7.29
Tightness of chest	1	0.52
Headache	1	0.52
Idiopathic dystonia	1	0.52
Insomnia	3	1.56
Itching and headache	1	0.52
Itching and swelling of face	1	0.52
Itching and vomiting	3	1.56
Maculopapular rash	11	5.72
MDR resistance	4	2.08
Megaloblastic anaemia	1	0.52
Itching	21	10.93
Rash and erythema	8	4.16
Rash, itching and headache	1	0.52
Respiratory distress	6	3.12
Severe headache	1	0.52
Shortness of breath	1	0.52
SJS	3	1.56
Slurred speech	1	0.52
Swelling of face and lips	1	0.52
TEN	4	2.08
Urticaria	4	2.08
Vomiting	4	2.08
Abdominal pain and vomiting	1	0.52

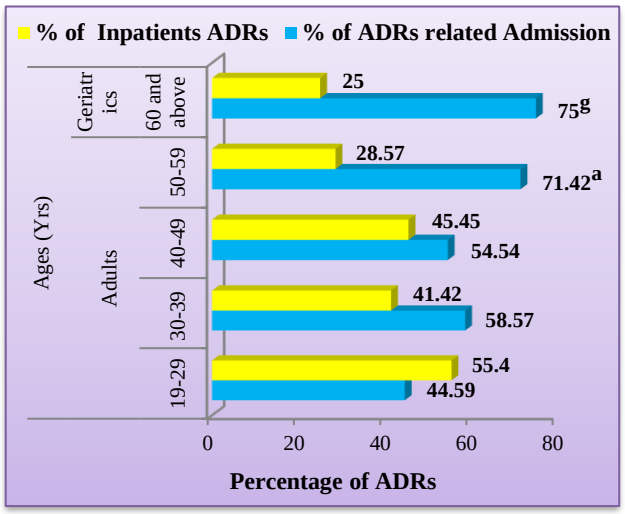
n=192 (Total no of adverse drug reactions), *=Highest no of adverse drug reactions (Skin rashes); FDE=Fixed drug eruption; EPS=Extrapyramidal Syndrome; TEN=Toxic epidermal nercolysis; SJS= Stevens-Johnson syndrome; MDR=Multidrug resistant

Table 2: Drugs VS adverse drug reactions.

Drugs	Reactions (No.)	%
5% dextrose IV	1	0.52
Aceclofenac tab	1	0.52
Aceclofenac/Paracetamol Tab	2	1.04
Aminoplasmal IV	7	3.64
Amoxicillin and Pot. Clavulanate Tab	5	2.60
Aripiprazole Tab	1	0.52
Astymin SN IV	1	0.52
Ayurvedic medicine powder	3	1.56
Azithromycin Tab	3	1.56
Carbamazepine CR Tab	1	0.52
Anti-TB schedule-1	14	7.29
Cefixime/Linezolide Tab	1	0.52
Cefpodoxime/Clavulanate Tab	1	0.52
Ceftazidime Inj	3	1.56
Ceftriaxone Inj	12	6.25
Chlorzoxazone/Paracetamol Tab	1	0.52
Ciprofloxacin IV	2	1.04
Ciprofloxacin/Tinidazole Tab	1	0.52
Cholecalciferol	1	0.52
Cotrimoxazole Tab	15	7.81
Diclofenec Tab	7	3.64
Furosemide Tab	1	0.52
Haloperidol Inj	3	1.56
Iron Sucrose IV	21*	10.93
LC/Mec/FA Tab	1	0.52
L/P/P/C Tab	1	0.52
Levosulpiride Tab	1	0.52
Meropenem Inj	1	0.52
Metronidazole IV	11	5.72
Nevirapine Tab	11	5.72
Nimesulide Tab	2	1.04
Norfloxacin Tab	1	0.52
Ofloxacin/Ornidazole Tab	10	5.2
Olanzapine Tab	6	3.12
Paracetamol Tab	12	6.25
Phenytoin Inj	4	2.08
Piroxicam Tab	1	0.52
Pregabalin Tab	2	1.04
Ranitidine Tab	1	0.52
Resperidone Tab	5	2.60
T/L/E Tab	2	1.04
Thyroxine Tab	1	0.52
Tramadol Inj	1	0.52
Ursodeoxycholic acid tab	1	0.52
Vancomycin Inj	2	1.04
Z/L/N Tab	6	3.12
Zoledronic acid Inj	1	0.52
Total	**192**	**99.89**

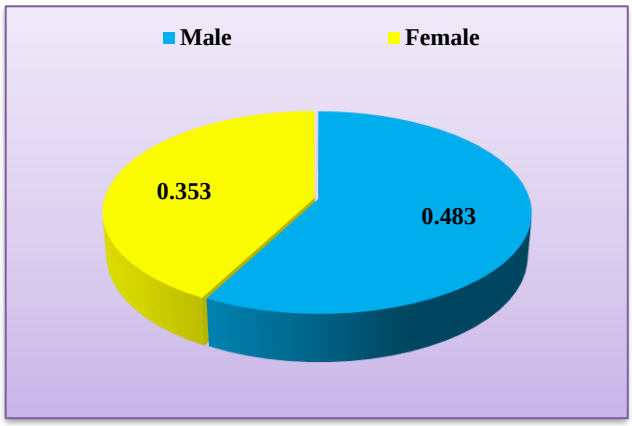
n=192 (Total no of adverse drug reactions); *=Highest no of adverse drug reactions due to Iron sucrose IV administration; T/L/E=Tenofovir/Lamivudine/Efavirenz; Z/L/N=Zidovudine/ Lamivudine/Nevirapine; L/P/P/C=Levocetrizine/Phenylephrine/Paracetamol/Caffeine; LC/Mec/FA=L-carnitine/ Mecabalamine /Folic acid; Anti TB schedule 1= Rifampicin, Pyrazinamide Isoniazid and Ethambutol.

A total number of 192 suspected ADRs were reported and analyzed from the patients as highest no of reaction, drugs causing more reaction, males, females, adults, geriatrics patients, severity assessment and type of adverse drug reactions etc. during the study period. The incidence of ADRs was observed in both ADRs induced hospital admissions and ADRs occurring during the hospital stay (Table 1 to Table 13 and Figure 1 and 2).



n=192 (Total no of adverse drug reactions); a= Adults age group (50-59 years) percentage of ADR related admission; g= Geriatric (More than 60 years) percentage of ADR related admission

Figure 1: Demographic details of the study population.



n=192 (Total no of adverse drug reactions)

Figure 2: No. and percentage incidence of ADRs.

DISCUSSION

The drug related complications are on the rise, warranting special attention towards patient's safety in tertiary care hospitals. As the patients, more likely to experience drug related complications are at the extremes of age, critically ill patients, patients with two or more organ failure, co morbidities, polypharmacy for long term illnesses, these factors make them more vulnerable to medication error

and drug interactions leading to ADRs. Hence, more intensive monitoring and reporting of ADR by Pharmacovigilance Program needs to be implemented.

The present study is a non-interventional, prospective, observational study conducted at a tertiary care hospital in southern part of Assam for a period of one year. During the study period a total number of 46962 patients were admitted to hospital. Out of 46962 patients, 192 patients were reported to have encountered ADRs.

In our study, spontaneous reporting method was used for detection of ADRs. Table 1 and 2 shows the details of the encountered ADRs reported by spontaneous method. The result revealed that, out of 192 ADRs detected during the study period, 24 (12.5%) Skin rashes, this is similar to the findings of previous studies where skin rashes constituted the maximum number of ADRs.[17]

We also reported, 21 (10.93%) itching, 19 (9.89%) Anaphylactic shock, 18 (9.37%) Erythema, 15 (7.81%) Extrapyramidal symptoms (EPS), 14 (7.29%) Fixed drug eruption, 11 (5.72%) Maculopapular rash, 8 (4.16%) Rash and erythema and 6 (3.12%) respiratory distress during the study period. These findings are almost similar to the previous studies.[18-21]

Most serious adverse drug reactions that were detected and reported during the study period were 4 (2.08%) Toxic Epidermal Necrolysis (TEN) and 3 (1.56%) Stevens-Johnson syndrome (SJS). In the previous studies have shown similar incidence of Steven Johnson Syndrome (SJS) is the most severe medical emergency, where the patients were having diffuse, exfoliating exanthema with generalized bulbous eruptions all over the body.[21]

Table 3: Gender distribution of ADRs.

Characteristics	No. of patients with ADR	Percent of patients with ADR
Male	97	50.52
Female	95	49.47

n=192 (total no of adverse drug reactions), among them 97 (50.52%) male and 95 (49.47%) Female.

The gender distribution (Table 3) of patients who had encountered ADRs during the study period at the study site showed that, the number and percentage 97(50.52) of ADRs were encountered in male patients and 95 (49.47) of the ADRs were encountered in the female patients. Result revealed that, there is no significance difference in the ADR occurance between the genders. Similar results had been reported in earlier studies.[22]

In present study, we have found that 103 (53.65%) of ADRs had lead to hospital admissions and 89 (46.35%) of ADRs had occurred during the hospital stay. This finding can be supported by earlier studies conducted by Sypros PD et al who also concluded that ADRs were the common causes of hospital admissions (Table 4).[23]

Table 4: ADRs related hospital admissions and ADRs reported during hospital stay.

No. of ADRs reported	No. (%) of ADR related admission	No. (%) of ADR reported during hospitalization
192	103 (53.65)*	89 (46.35)

n=192 (Total no of adverse drug reactions); *=Highest number and percentage of ADRs induced hospital admission.

Table 5 shows, a maximum number of 184 (95.83%) adult patients had encountered ADRs. Out of which 97 (52.71%) ADRs had lead to hospital admissions and 87 (47.28%) of ADRs occurred during the hospital stay. Results also revealed that in the geriatric patients, 8 (4.16%) had encountered ADRs, out of which 6 (75%) ADRs lead to induced hospital admissions and 2 (25%) of ADRs occurred during the hospital stay at our study site.

Table 5: Percentage of ADRs in adults and geriatrics patients.

Groups	No. (%) of ADRs	% of ADRs related admission	% of ADRs occur during hospitalization
Adults(a)	184	97 (52.71) [a]	87 (47.28)
Geriatric (g)	8	6 (75) [g]	2 (25)

n=192 (Total no of adverse drug reactions); a=% of adult patients hospitalization due to ADRs; g=% of geriatric patients hospitalization due to ADRs.

In Figure 1 shows, the number and percentages of ADRs that had lead to hospital admissions and ADRs that occurred during hospital stay in adult age group and geriatric patients. In the age group of 19-29 Yrs, [33 (44.59%)] ADRs had lead to induced hospital admissions and 41 (55.40%) of ADRs had occurred during the hospital stay. In the age group of 30-39 yrs, 41 (58.57%) ADRs had lead to hospital admissions and 29 (41.42%) of ADRs had occurred during the hospital stay. In the age group of 40-49 yrs, 18 (54.54%) of ADRs had lead to hospital admissions and 15 (45.45%) of ADRs had occurred during the hospital stay. In the age group of 50-59 yrs, 5 (71.42%)[a] of ADRs had lead to hospital admissions and 2 (28.57%) of ADRs had occurred during the hospital stay. In the geriatric age group, 6 (75%)g of ADRs had lead to hospital admissions and 2 (25%) of ADRs had occurred during the hospital stay.

This study is in compliance with the earlier studies where higher rates of ADR were found in elderly patients who are likely to be receiving multiple medications for long-term illnesses making them more vulnerable to incidence of ADRs.[24-26]

It was seen that most of the ADRs were reported from the Departments of Dermatology 83 (43.22*%) followed by other departments like Medicine 36 (18.75%), Obstetrics and Gynaecology 29 (15.1%), Psychiatry 16 (8.33%), TB 14 (7.29%), Surgery 9 (4.68%), Emergency 3 (1.56%), ENT and Paediatrics 1 (0.52%) etc. (Table 6).

Table 6: Distribution of ADRs among various department wards in hospital.

Department Wards	No. of ADRs	Percent of ADRs
Dermatology	83	43.22*
Medicine	36	18.75
Obstetrics and Gynaecology	29	15.1
Psychiatry	16	8.33
TB	14	7.29
Surgery	9	4.68
Emergency	3	1.56
ENT	1	0.52
Paediatric	1	0.52

n=192 (Total no of adverse drug reactions); *=Highest Percentage of ADRs; TB=Tuberculosis; ENT=Ear nose and throat.

Most of the patients reported to Dermatology department, as they might been attending Dermatology OPD or been referred from other departments. As predicted the bulk of ADRs were reported from medicine department as it is a department that relies on drug therapy to the maximum. The above results slightly differ from the previous study where they found most reaction reported by medicine department followed by other departments.[27]

Table 7: Classification of ADRs according to Wills and Brown.

Types of ADR	No. of ADRs reported	Percent of ADRs
Type A (Augmented)	45	23.43
Type B (Bugs)	4	2.08
Type C (Chemical)	0	0
Type D (Delivery)	0	0
Type E (Exit)	0	0
Type F (Familial)	0	0
Type G (Genetotoxicity)	0	0
Type H (Hypersensitivity)	140	72.91*
Type U (Unclassified)	3	1.56

n=192 (Total no of adverse drug reactions); *=Percentage type of ADRs.

Table 7 shows, the type of ADRs that were classified according to Wills and Brown method of classification. This method data revealed that the maximum number of hypersensitivity reaction (Type H reactions) 140 (72.91* %) which are not preventable followed by Augmented reactions, also called Type A reaction 45 (23.43%) these reactions are predicted by known pharmacology of the drug, Type B reaction 4 (2.08%) and Type U (unclassified) 3 (1.56%) at our study site. These findings were similar to the previous study conducted by Arulmani et al which shows higher incidence of Type H reactions.[28]

Table 8: Causality assessment of ADRs.

Causality parameters (WHO Scale)	No. (%) of ADRs reported	Percent
Certain	4	2.08
Probable	104	54.16*
Possible	75	39.06
Unassessable/ Unclassifiable	5	2.6
Unlikely	4	2.08
Conditional/ Unclassified	0	0

n=192 (Total no of adverse drug reactions); *= Probable percentage of ADRs.

Casual relationships were assessed by WHO Causality Assessment Scale. Majority of the ADRs belonged to probable 104 (54.16*%) followed by possible 75 (39.06%), unassessable/unclassifiable 5 (2.6%), certain and unlikely 4 (2.08%) (Table 8).

Table 9: Severity assessment of ADRs.

Level of severity (HARTWIG Scale)	No. of ADRs reported	Percent
Mild	42	21.87
Moderate	79	41.14*
Severe	71	36.97

n=192 (Total no of adverse drug reactions); *=Moderate percentage of ADRs.

Severity of the ADRs encountered during the study period was determined by using the Hartwig's Severity Assessment Scale**.** The results of assessment of the severity suggested that maximum number of ADR encountered were found to be moderate 79 (41.14%), followed by 71 (36.97%) ADRs which were severe and 42 (21.87%) which were mild. Severities of ADRs are illustrated in the Table 9. During the study period no fatal and life-threatening adverse reactions were reported.

Thus, adverse reactions reported in the present as well as other studies underline the importance of such studies and need for creating awareness among healthcare professionals for reporting such reactions.[29]

Table 10, shows that the most common drug class associated with ADRs were Antimicrobials 101 (52.6%), which was found to have mostly affected the Skin system followed by NSAIDs 24 (13.54%), Haematinic 21 (10.93%), others 19 (9.89%), Antipsychotic 16 (8.33%), Antiepileptic 7 (3.64%), Antihistaminic and Diuretic 1 (0.52%). Antimicrobial drugs are most commonly prescribed in hospitalized patients. Majority of the patients

treated in hospitals receive at least one antibiotic and a significant proportion of them either receive two or more. This practice leads to increased chances of ADR's in patients. Antimicrobials were found to be more affecting class of drugs in this study, inducing 101 ADRs. The study results correspond to similar studies on comparable population.[30-33]

Table 10: Drug class most commonly associated with ADRs.

Drug class	No. of ADRs reported	Percent of ADRs
Antimicrobials	101	52.6*
NSAIDs	26	13.54
Haematinics	21	10.93
Antipsychotics	16	8.33
Antiepileptics	7	3.64
Antihistaminics	1	0.52
Diuretics	1	0.52
Others	19	9.89

n=192 (Total no of adverse drug reactions); *=Maximum percentage of ADRs with antimicrobials class of drug

Table 11, outcome of the reaction showed that out of 192 ADRs, 172(89.58%) ADRs were fully recovered followed by 20 (10.41%) ADRs status were unknown, which shows better management of drug therapy. Most serious ADRs were Skin rashes (suspected for Steven Johnson Syndrome and toxic epidermal necrolysis) which were recovered later. Outcomes of present study corresponds with two Indian studies.[34,35]

Table 11: Outcome of patients.

Outcomes	No. of patients	Percent
Fatal	0	0
Recovered	172	89.58
Unknown	20	10.41

n=192 (Total no of adverse drug reactions)

Overall incidence of ADRs in present study was found to be 0.41% of which 0.22% ADRs had lead to induced hospital admissions and 0.19% of ADRs occurred during the hospital stay (Figure 2). These findings were slightly lower than the reports generated from other Indian studies and reported by Vora M et al.[36-38] However, ADRs related hospital admission was 1.72% which is lower as compared to previous studies. This can be attributed to the fact that the study was conducted over particular inpatients department excluding all other speciality departments of hospital. Also, duration of the study was short of just six months. Lower incidence rate in our study may be due to lack of awareness regarding the practice of pharmacovigilance and under reporting of ADRs.

CONCLUSION

Hospital based monitoring of ADR and reporting is an important program to identify and quantify the risks associated with the use of drugs. This information may be useful to identify and minimize the preventable ADRs, and at the same time enhancing the knowledge of the prescribers to deal with ADRs more actively and efficiently.

- There is a gradual increase in the ADR reports in recent times, though it is too early to say unless the upward trend continues in the future.
- Overall, low proportions of the estimated ADRs are getting reported.
- Low awareness about the PvPI, busy schedule and reluctance to reporting among the healthcare professionals is perceived as the main cause of under-reporting of ADRs.
- Mostly Doctors, PGTs and Nurses are reporting ADRs; however, pharmacist and other health care authorities are also required to take active part in reporting ADRs.
- There are problems pertaining to the complications of ADR forms resulting in incomplete filling of ADR forms. This can be minimized by organizing workshops and sensitizing health care professionals regarding the proper filling of ADR forms and emphasizing on the importance of such reporting
- The need for the proper functioning and sustainability of the PvPI rest on the active reporting of any suspected case of ADR by the healthcare professionals.
- There is low reporting of ADRs in the Geriatric age groups even though the percentage of ADR related hospital admissions was highest in this group

Early identification and management of ADRs are essential to avoid complications and severity. Special attention is required to be taken for the patients who are in poly-pharmacy. Whenever an ADR is encountered the first step to be employed is to reduce the drug dose or withdraw the drug altogether.

The Pharmacovigilance programme which has been started and running quite well in our country, still the healthcare professional are unaware about the monitoring and reporting of ADRs. By regulating the current system of Pharmacovigilance and conducting various workshops on its awareness, the importance of ADR reporting can reduce the incidence of ADRs in hospitalised patients and ADRs induced hospitalization.

Under reporting the ADRs in the present study revealed that, more awareness about the importance of Pharmacovigilance have to be provided among the health care professionals by way of ADR bulletins, seminars and workshops.

There is need for establishing ADRs monitoring centre at every multidisciplinary hospital including peripheral healthcare centre. Also, more studies need to be conducted in Indian population to know the exact prevalence of ADRs in Indian hospitals.

ACKNOWLEDGMNTS

The author extends thanks to ADRs Monitoring Centre, Pharmacovigilance Programme of India under Indian Pharmacopoeia Commission and health care professionals from various departments of Silchar Medical College and Hospital for their help and support during the study.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Laskar JI, Chakravarty P, Dewan B. A study on incidence of adverse drug reactions with commonly prescribed drugs and causality assessment in Silchar Medical College and Hospital. Int J Basic Clin Pharmacol 2017;6:1175-83.