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ORIGINAL ARTICLE

A study on adverse drug reactions in a tertiary care hospital of Northeast India

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KEYWORDS

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Northeast;
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Abstract *Objective:* Purpose of this study was to monitor adverse drug reactions reported from various departments of a tertiary care hospital in Northeast India. Reported adverse drug reactions were analysed for causality and severity assessment.
Methods: This cross sectional study was conducted in a tertiary care hospital at Guwahati, Northeast India, for 7 months. Patients of all age and either sex were included. Adverse drug reactions were reported by the physicians of this hospital and their causality and severity assessments were performed as per Naranjo's and Hartwig's assessment criteria respectively. Descriptive statistics were used for data analysis.
Results: Total 255 adverse drug reactions were reported from various departments of this tertiary care hospital. Most of the adverse drug reactions were observed in the age group of 21–30 year. Acne (46) was commonly reported reaction. Topical steroids, betamethasone sodium phosphate and clobetasol were reported to induce maximum number of reactions (59). Skin (227, 66.9%) was commonly affected organ system. Most of the adverse drug reactions were possible (240, 94.1%) and mild (222, 87%) in nature.
Conclusions: The topical steroid (betamethasone sodium phosphate) was reported to induce adverse drug reactions in majority of the patients. The commonly reported reaction was acne.

1. Introduction

Drugs prescribed for disease are often themselves the cause of serious amount of adverse reactions ranging from mere inconvenience to permanent disability and death. According to DJP Barker, "There are three actions of a drug: The one you want,

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the one you don't want, and the one you don't know about".[1] Since drugs are intended to relieve suffering, patients find it particularly offensive that they can also cause disease. It has been reported that ADRs account for 5% of all hospital admissions and occur in 10–20% of hospitalized patients.[2] An overall incidence of serious and fatal ADR among hospitalized patients is 6.7% and 0.32%, respectively.[3] Sometimes, ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications.[4] The recent epidemiological studies have estimated that adverse drug reactions are the fourth to sixth leading causes of death.[5] Moreover, detection of ADRs has become increasingly significant because of introduction of a large number of potent toxic chemicals as drug in last two or three decades. Thus, it became very crucial to monitor both known and unknown adverse effects of medicines.

As per WHO, pharmacovigilance is an activity concerned with the detection, assessment, understanding, management and prevention of adverse reactions to medicines, contributes to their safe and rational use.[6] ADR can also be defined as "an appreciably harmful or unpleasant reaction, resulting from intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product." Though ADRs are of great concern to the general public, medical profession, pharmaceutical industry and regulatory authorities, the concept of ADR reporting is still new in India and reporting of ADRs is scarce. Govt. of India under the aegis of Ministry of Health & Family Welfare has also initiated Pharmacovigilance Programme of India and established adverse drug reaction monitoring centres in various tertiary care hospitals across the country to monitor ADRs.[7] Northeast region comprised of 8 Indian states with varied tribal community and ethnicity. However, from this region still there is underreporting of ADRs. Hence, this study was undertaken to record and analyse adverse drug reactions reported from various departments of a tertiary care hospital situated at Guwahati, known as gateway to Northeast India. We have also analysed ADRs for causality and severity.

2. Methods

An observational, cross-sectional study was carried out for 7 months from January 2015 to July 2015 at outpatient and inpatient setting of a tertiary care hospital in Guwahati, Northeast India. Permission from Institutional Ethical Committee of the hospital was obtained prior to the initiation of this study. ADRs were reported from outpatient departments as well as from wards of cardiology, dermatology, gynaecology, haematology, medicine, ophthalmology, paediatric, psychiatry, TB and chest, and neurology department of the hospital. The contact number and email id of study authors were circulated among the physicians of respective departments to facilitate reporting of ADR. Those cases which were identified and reported by physicians of this hospital were considered as an ADR and recorded. The collected information included patient's initial, age, gender, reporting department of the hospital, description of the reaction, duration of reaction, name of the suspected drug causing reaction, and outcomes. Drugs causality assessment was performed by Naranjo's probability assessment scale[8] and Hartwig's criterion[9] was used for severity assessment. Rechallenge was not attempted in any patient. Outcome of the patients with ADR were recorded as fatal, fully recovered (patient fully recovered during study period), recovering (patient recovering, but not fully recovered during study period) and unknown (insufficient information and not documented).

2.1. Inclusion criteria

All the suspected ADRs that may be due to the medications, both prescribed and over the counter, taken by patients either as inpatients or outpatients, that were ultimately noted.

2.2. Exclusion criteria

The use of alternative system of medicines such as Ayurveda, Homeopathy, Unani, etc. as well as over prescribing, over dosage, excess consumption and patients taking more than ten prescription drugs were excluded. All mentally retarded, drug addicted, and unconscious patients were also excluded from the study. Patients admitted due to alcohol or drug abuse, a suicide attempt or admissions planned more than 24 h in advance were not recorded.

Naranjo ADR probability scale for causality assessment.[8]

		Yes	No	Do not know
1	Are there previous conclusive reports on this reaction?	+1	0	0
2	Did adverse event appear after the suspected drug was administered?	+2	−1	0
3	Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0
4	Did the adverse reaction appear when the drug was readministered?	+2	−1	0
5	Are there any alternative causes (other than the drug) that could on their own have caused the reaction?	−1	+2	0
6	Did the reaction reappear when placebo was given?	−1	+1	0
7	Was the drug detected in the blood (or other fluids) in concentration known to be toxic?	+1	0	0
8	Was the reaction more severe when the dose was increased or less severe when the dose is decreased?	+1	0	0
9	Did the patient have a similar reaction to the same drug or similar drugs in any previous exposure?	+1	0	0
10	Was the adverse event confirmed by any objective evidence?	+1	0	0

ADR probability classification	Score
Causality assessment score	
Definite	9
Probable	5–8
Possible	1–4
Doubtful	0

Table 1 Age and gender wise distribution of patients with ADRs.

Age range	Male	Female	Total patients (%)
⩽1–10	7	4	11(5.0)
11–20	19	15	34(15.5)
21–30	31	51	82(37.4)
31–40	18	27	45(20.5)
41–50	13	17	30(13.6)
51–60	9	3	12(5.4)
⩾61	4	1	5(2.2)
Total patients	101	118	219

Hartwig severity assessment scale.[9]

As per this scale ADRs were classified as follows:

1 Mild reactions which were self limiting and able to resolve over time without treatment and did not contribute to prolongation of length of stay.
2 Moderate ADRs were defined as those that required therapeutic intervention and hospitalization prolonged by 1 day but resolved in <24 h or change in drug therapy or specific treatment to prevent a further outcome.
3 Severe ADRs were those that were life threatening, producing disability and those that prolonged hospital stay or led to hospitalization, required intensive medical care, or led to the death of the patient.

2.3. Statistical analysis

Description statistics were used for data analysis. For non-normally distributed continuous data, median (interquartile range) was calculated.

3. Results

In this study, 303 patients were reported to experience ADR during study period. Eighty-four ADR cases were discarded from the study because in these cases more than one offending drug was suspected. Out of 219 patients, 101 (46.1%) patients were male while 118 (53.8%) patients were female. Of which, 124 patients had single ADR followed by 73 patients who were with two ADRs, 19 patients who were with three ADRs and 3 patients who were with four ADRs. Most of the patients (91.7%) were reported from outpatient departments and rests (8.2%) were reported from inpatient department admitted to various wards of the hospital. The median age of the patients was 29 (18). The youngest patient was of 4 months and oldest of being 76 years. Majority of the patients (37.4%) experienced ADRs belonged to age group of 21–30 years (Table 1). According to department wise distribution of patients with ADRs, majority of the patients with ADR were reported from dermatology department (63.01%) followed by haematology department (18.26%), and psychiatry department (11.87%) (Table 2).

In this study, 255 ADRs were reported from various departments of the hospital (Table 3). The median duration of the ADR was 20(29). Out of total ADRs, commonly reported ADR was acne (18.03%) followed by itching (7.84%) and melasma (5.1%). The topical steroid (betamethasone sodium phosphate) was reported to cause majority of ADRs (23.13%) followed by topical steroid (clobetasol propionate) (9.41%), imatinib (5.88%), derobin ointment (salicylic acid) (3.92%) and paracetamol (3.13%) (Table 3). Skin was the most commonly affected organ system (63.52%) followed by nervous system (15.29%), digestive system (8.62%), and cardiovascular system (2.35%) (Table 4).

Table 2 Department wise distribution of patients with ADRs.

SI. no.	Departments	Number of patients with ADR (%), $N = 219$
1	Dermatology	138(63.01)
2	Haematology	40(18.26)
3	Psychiatry	26(11.87)
4	Medicine	3(1.36)
5	TB & Chest	3(1.36)
6	Cardiology	2(0.91)
7	Gynaecology	2(0.91)
8	Paediatric	2(0.91)
9	Neurology	2(0.91)
10	Ophthalmology	1(0.45)

According to the Naranjo's algorithm scale, 240(94.1%) suspected ADRs were possible, 10(3.9%) ADRs were probable, and 2(0.7%) ADRs were definite. As per Hartwig severity assessment scale, majority of the ADRs were mild (222, 87.0%), 32 (12.5%) ADRs were moderate, and 1(0.3%) ADR report was severe. Most of the patients with ADR (239, 93.7%) were completely recovered after treatment and 10(3.9%) ADRs were classified as 'unknown outcomes' due to lack of follow-up and incomplete information (Table 5).

4. Discussion

In our study, 231 suspected offending drugs were reported to induce various ADRs. Of which majority (92.6%) of the drugs were withdrawn for the management of ADR and rechallenge was not performed in any patient. Majority of ADRs were reported from female patients than from male. Paediatric[10] and geriatric[11] patients are vulnerable groups, supposed to experience ADR more often. However, in our study adult patients belonged to age group of 21–30 years were reported to experience maximum number of ADRs. It is likely that this population is attending hospital more frequently and is a major population receiving drug therapy.

This study was conducted in one of the tertiary care hospitals of Northeast India and there is likely to be variation between different hospitals because of differences in the local population characteristics and the specialties within the hospitals. In this hospital, most of the ADRs were reported from dermatology department. It was observed that the patients with cutaneous ADRs were referred to dermatology department by the physicians of other department, and thus this may have resulted into high reporting form dermatology department of this hospital. In general, medicine department relies on drug therapy to the maximum. However, low reporting (1.7%) was observed from medicine department. From

Table 3 Suspected drugs and their reported ADRs.

Sl. no.	Suspected drugs	Number of ADRs, $N = 255$	ADRs (frequency of occurrence)
1	Betamethasone sodium phosphate (topical)	58	Acne(23), Itching(3), Erythematous Skin rash(2), Aggravated tinea, Melasma(10), Hypertrichosis(3), Telangiectasis(4), Freckles, Rosacea, Skin Atrophy(2), Hyperpigmentation, Acneiform lesions, Skin erosion, Skin Striae(2), Dandruff, Truncal Acne, Acneform eruption
2	Clobetasol propionate (topical)	24	Acne(11), Eczema over hand, Erythema, Dry skin (2), Skin rash (purpurea), Skin fissures with erythema, Rosacea, Allergic reaction, Melasma, Aggravated Acne (4)
3	Imatinib	15	Skin discolouration, Blackness of skin (4), Scrotal edema, Abdominal swelling, Erythematous skin rash (2), Diarrhoea, Pain in leg, Bone marrow suppression, Itching over head, Mucositis, Headache
4	Derobin ointment (Salicylic acid-1.15%, Dithranol-1.15%, Coal tar-5.3%)	10	Dermatitis, Itching, Irritant Contact dermatitis (7), Tinea Incognito
5	Paracetamol	8	Fixed drug eruption(5), Erythema, Itching over hands & palms, Skin rashes
6	Bortezomib	7	Pneumonia with respiratory distress, Vision problem, Knee pain, Burning sensation in chest, Constipation, Tastelessness, Oral ulcers
7	Cytarabine	6	Pancytopenia, Hypersensitivity, Mucositis, Neutropenia, Knee pain, Reddening of legs
8	Mometasone furoate	6	Dermatitis, Itching(2), Erythema, Papular eruption, Photosensitivity
9	Cefixime trihydrate	6	Toxic Epidermal Necrolysis (TEN), Burning sensation, Hyperpigmentation, Skin rash, Urticaria, Fever
10	Phenytoin sodium	6	Lichenoid Drug Eruption, Erythema, Papular lesions, Maculopapular Skin rash, Exfoliative dermatitis, Gum hypertrophy
11	Clobetasol butyrate (topical)	6	Acne (5), Facial dermatitis
12	Methotrexate	5	Diarrhoea, Hair loss, Weight loss, Bullous Skin rashes, Mucositis
13	Prednisolone acetate	5	Acne (3), Comedones, Rosacea
14	Ketoconazole	4	Erythema, Papular lesions, Itching, Burning sensation
15	Triderm ointment (Gentamycin sulphate-0.5 mg, Betamethasone dipropionate-0.64 mg, Clotrimazole-10 mg) (topical)	4	Atrophy, Erythematous skin rashes(2), Hyperpigmentation
16	Fluconazole	4	Erythematous skin rashes (2), swelling on scrotal skin, Skin rash
17	Diprovate-N ointment (Betamethasone 0.05% + Neomycin sul. 0.5%)	4	Erythematous maculopapular lesions(2), Itching(2)
18	Olanzapine	4	Extrapyramidal Symptoms (2), excessive sedation, Urinary retention
19	Clonazepam	3	Palpitation, Decreased sleep, Dryness of mouth
20	Diclofenac gel	3	Irritant Contact dermatitis (2), herpes zoster
21	Betamethasone dipropionate (topical)	3	Acne (2), Freckles
22	Risperidone	3	Extrapyramidal symptoms (2), Vomiting
23	6 Mercaptopurine	3	Diarrhoea, Erythrocytopenia, Jaundice
24	Iron-Sucrose Inj. (Saccharated iron oxide)	3	Rigor, Vomiting, Pain at infusion site
25	Cycloserine	3	Restlessness, Suicidal tendency, Vomiting
26	Haloperidol	3	Akathisia, Extrapyramidal Symptoms (2)
27	Naltrexone	2	Decreased appetite, Episodic Irritability
28	Dexamethasone	2	Abnormal hair growth on face, Adrenal suppression
29	Herbal Medication (topical)	2	Skin Rash, Aggravated Plaque over scalp
30	Hydrocortisone	2	Melasma, Acne
31	Clobetamil-G ointment (Clobetasol propionate-0.05%, Gentamycin sulphate-0.1%)	2	Melasma, Hyperpigmentation
32	Aculip-H	2	Disturbed sleep, Crawling sensation
33	Temovate ointment (Clobetasol Propionate)	2	Papular Rash, Erythema
34	Homeopathic & Ayurvedic Medicine (topical)	2	Skin Rash, Itching
35	Valproin Syrup (Valproate sodium)	2	Steven Johnson's Syndrome, Skin rash
36	Doxycycline	2	Itching, Photosensitive allergic reaction
37	Vaccine DPT (Tetanus/Diphtheria/Pertussis)	2	Fever, Seizures
38	Diclofenac Sodium	2	Fixed Drug eruption, Urticaria

Table 3 (*continued*)

Sl. no.	Suspected drugs	Number of ADRs, $N = 255$	ADRs (frequency of occurrence)
39	Zincofer (Ascorbic acid/Pyridoxin HCl/Folic Acid/ Ferrous fumarate, etc.)	2	Giddiness, Headache
40	Triglow Cream (hydroquinol with tretinoin fluocinolone acetonide)	2	Telangiectasis, Acneform rash
41	Blood transfusion	2	Fever, Rigor
42	Mustard Oil (Brassica Nigra seed oil)	2	Oedema, Exfoliative dermatitis
43	Rituximab	1	Respiratory paralysis
44	Lenalidomide	1	Diarrhoea
45	Cyclosporine	1	Kidney dysfunction
46	Candid B ointment (Beclomethasone dipropionate 0.025% + Clotrimazole 1%)	1	Irritant contact dermatitis
47	Ayurvedic Medication (topical)	1	Itching
48	Olay Complete defence moisturizing lotion (Zinc oxide/Octinoxate)	1	Itching
49	Cortisone acetate	1	Acneform eruption
50	Karpin lotion (Tartaric acid-2%, Phenol-0.2% in aq.soln.)	1	Contact dermatitis
51	Betamil-GM ointment (Betamethasone dipro.-0.05%, Gentamycin sulph. 0.1%, Miconazole nitra.2%)	1	Eczematoid dermatitis
52	L-asparaginase	1	Abdominal pain
53	Minoxidil lotion	1	Dizziness
54	Sodium valproate	1	Mucositis
55	Methyl prednisolone	1	Hyperglycaemia
56	B-tex lotion(salicylic acid-10%, camphor, boric acid)	1	Contact dermatitis
57	Gatifloxacin eye drops	1	Allergic contact dermatitis
58	Clobetasol propionate (topical)	1	Acne
59	Targocid	1	Anaphylactic reaction

Table 4 Organ system affected by ADRs.

Organ system	Number of ADRs (%), $N = 255$
Skin	162(63.52)
Nervous	39(15.29)
Digestive	22(8.62)
Cardiovascular	6(2.35)
Genitourinary	2(0.78)
Respiratory	2(0.78)
Endocrine	1(0.39)
Musculoskeletal	1(0.39)
Other	20(7.84)

Table 5 Causality and severity assessment of ADRs and their outcomes.

Parameters	Number of ADRs (%), $N = 255$
Causality	
Doubtful; $\leqslant 0$	3(1.1)
Possible; 1–4	240(94.1)
Probable; 5–8	10(3.9)
Definite; $\geqslant 9$	2(0.7)
Severity	
Mild	222(87.0)
Moderate	32(12.5)
Severe	1(0.3)
Outcomes	
Recovered	239(93.7)
Continuing	5(1.9)
Recovering	0(0)
Unknown	10(3.9)
Fatal	1(0.3)

previous studies, commonly reported cutaneous ADRs were urticaria, fixed drug eruptions, acneform eruptions, maculopapular rashes, and Steven Johnson syndrome (SJS).[12,13] In this study, acne, itching, melasma, contact dermatitis, rashes, and erythematous rashes were commonly reported ADRs among cutaneous reactions. As reported, SJS and toxic epidermal necrolysis (TEN) are rare but potentially life threatening serious ADRs.[14] In our study, one report of each SJS and TEN was reported due to valproate sodium and cefixime trihydrate respectively. As reported, skin is the most commonly affected organ system.[15] In agreement with this, in our study most of the patients have experienced skin disorder.

In this study, majority of the ADRs were associated with topical application of drug. Topical steroid ointment containing betamethasone propionate, and clobetasol were commonly reported to induce acne, itching, erythematous rash, aggravated tinea, melasma, hypertrichosis, telangiectasis, freckles, rosacea, skin atrophy, hyperpigmentation, acneiform lesions, erosion, striae, dandruff, truncal acne, acneform eruption, and dry skin. Paracetamol is also reported as one of the offending drugs to induce fixed drug eruption, erythema,

itching over hands and palms, and rashes. The ADR reports of lichenoid drug eruption, erythema, papular lesions, maculopapular skin rash, exfoliative dermatitis, and gum hypertrophy were reported due to phenytoin sodium. Beside these, cytarabine induced pancytopenia, hypersensitivity, mucositis, neutropenia, knee pain, and reddening of legs were commonly reported from haematology department of this hospital.

According to Naranjo's scale, from south Indian studies[16,17] most of the reported ADRs were probable, where in this study most of the ADRs (93.7%) were classified as possible, and only 10 ADR reports were probable. As per Hartwig criteria most of the ADR reports were mild in nature and recovered during study period. Very few ADRs (1.9%) were not recovered.

In this hospital, it was observed that the documentation of ADRs were unintentionally get missed which could be because of work related stress and forgetfulness, lack of knowledge and awareness about the importance of drug safety monitoring, poor knowledge of ADR reporting programme objectives, and busy outpatient setting, and many clinicians do not consider reporting a priority. This study suffers the main drawback of spontaneous reporting system i.e. underreporting. Thus, ADR monitoring should be strengthened in this diversified region by sensitizing and encouraging healthcare providers to report ADRs.

5. Conclusion

The topical steroid (betamethasone sodium phosphate) was reported to cause majority of ADRs. The commonly reported ADR in this study was acne. This study suggests that there is a need of spontaneous ADR reporting from all the departments of this tertiary care hospital for monitoring and assessment of ADRs. This study also warrants further research in this part of India for the development of possible intervention strategies to reduce burden of ADRs.

Conflict of interest

None.

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References

1. Gupta SK. *Post marketing surveillance text book of pharmacovigilance*. first ed. Jaypee Brothers Medical Publishers(P) Ltd; 2011. p. 75.
2. Einarson TR. Drug-related hospital admissions. *Ann Pharmacother* 1993;**27**(832–84).
3. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA* 1998;**279**:1200–5.
4. World Health Organization. Fact sheet No293. Medicines: safety of medicines – adverse drug reactions. Geneva: World Health Organization; 2008.
5. Srinivasan R, Ramya G. Adverse drug reaction causality assessment. *Int J Res Pharm Chem* 2011;**1**(3):606–11.
6. World Health Organization. Pharmacovigilance. Available from: <http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/index.html> accessed 10 January 2015.
7. Lihite RJ, Lahkar M. An update on pharmacovigilance programme of India. *Front Pharmacol* 2015;**6**:194.
8. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, et al. A method for estimating the probability of adverse drug reactions. *Clin Pharmacol Ther* 1981;**80**:289–95.
9. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. *Am J Hosp Pharm* 1992;**49**:2229–32.
10. Priyadharsini R, Surendiran A, Adithan C, Sreenivasan S, Sahoo FK. A study of adverse drug reactions in pediatric patients. *J Pharmacol Pharmacother* 2011;**2**:277–80.
11. Mandavi, D'Cruz S, Sachdev A, Tiwari P. Adverse drug reactions & their risk factors among Indian ambulatory elderly patients. *Indian J Med Res* 2012;**136**:404–10.
12. Sushma M, Noel MV, Ritika MC, James J, Guido S. Cutaneous adverse drug reactions: a 9-year study from a South Indian Hospital. *Pharmacoepidemiol Drug Saf* 2005;**14**:567–70.
13. Lihite RL, Lahkar M. A study on cutaneous adverse drug reactions in ADR monitoring centre of tertiary care hospital, Guwahati. *J Appl Pharm Sci* 2013;**3**:79–81.
14. Lihite RJ, Lahkar M, Borah A, Hazarika D, Singh SM. A study on drug induced Stevens–Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and SJS-TEN overlap in a tertiary care hospital of Northeast India. *J Young Pharm* 2016;**8**(2), 1-1.
15. Rehan HS, Chopra D, Sah RK, Mishra R. Adverse drug reactions: trends in a tertiary care hospital. *Curr Drug Saf* 2012;**7**:384–8.
16. Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. *Br J Clin Pharmacol* 2008;**65**:210–6.
17. Shrivastava M, Uchit G, Chakravarti A, Joshi G, Mahatme M, Chaudhari H. Adverse drug reactions reported in Indira Gandhi Government Medical College and Hospital, Nagpur. *J Assoc Physicians India* 2011;**59**:296–9.