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Evaluation of cutaneous drug reactions in patients visiting out patient departments of Indira Gandhi Government Medical College and Hospital (IGGMC and H), Nagpur

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Abstract

Objectives: To detect cutaneous drug reactions through spontaneous reporting system in IGGMC and H, Nagpur and analyze them using standard assessment scales. **Materials and Methods:** An observational, prospective study was performed in patients attending dermatology OPD of IGGMC and H, Nagpur from 1st June 05 to 31st May 09. Patients were examined for cutaneous drug reactions (CDRs) by spontaneous Adverse Drug Reaction reporting system. **Results:** Among 2693 total ADRs reported, 872 (33.04%) were CDRs. Antimicrobials (55.5%) were the main drugs involved followed by NSAIDs (18.56%) and steroids (12.61%). Maculopapular rash (37.73%) followed by fixed drug eruption (17.2%) and urticaria (14.56%) were the most frequently observed CDRs. The common drugs causing CDRs were cotrimoxazole (20.41%), topical steroids (betamethasone), ibuprofen (7.91%), ampicillin (6.54%), diclofenac (4.7%) and iron dextran (3.44%). **Conclusion :** It was observed that commonly used drugs like antibiotics and NSAIDs lead to maximum number of CDRs. Hence strict vigilance is required while using them. This study provides a database of ADRs due to common drugs, which will help clinicians in safe use of these drugs.

Keywords: Cutaneous drug reactions, pharmacovigilance, spontaneous ADR reporting

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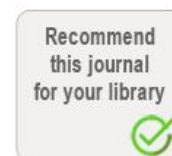
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What was known?

Maculopapular rash and urticaria are common form of CDRs. Antimicrobials, antiepileptic drugs and NSAIDs are most common offending drugs for CDRs.

Introduction[top](#)

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Cutaneous drug reactions are among the most frequent adverse drug reactions. Cutaneous drug reactions (CDR) occur in approximately 2-6% of all patients treated. [1] Maculopapular rash represent the majority of CDR (95%), followed by urticaria (5%). [2] Although virtually any drug is capable of eliciting an adverse cutaneous reaction, the most frequently implicated agents are antimicrobials and non-steroidal anti-inflammatory drugs (NSAIDs). [3] Prompt recognition of these reactions, drug withdrawal, and appropriate therapeutic interventions can minimize toxicity.

Although adverse drug reactions are common, it is difficult to ascertain their incidence, seriousness, and ultimate health effects. Available information comes from evaluations of hospitalized patients, epidemiologic surveys, premarketing studies, and voluntary reporting, most notably to the U.S. Food and Drug Administration's Medwatch System. In a systematic literature review of cutaneous reactions to drugs, the reaction rates varied from 0 to 8% and were highest for antibiotics. In a series of 48005 patients over a 20-year period, maculopapular rash (91%) and urticaria (6%) were the most frequent skin reactions. [4]

The relative risk of Stevens-Johnson syndrome [More Details](#) (SJS) and toxic epidermal necrolysis (TEN), perhaps the most important severe cutaneous reactions, has been quantified in an international case control study and case series. Sulfonamide antibiotics, amine antiepileptic drugs (phenytoin and carbamazepine), lamotrigine, and the oxycam nonsteroidal anti-inflammatory drugs (NSAIDs) are associated with the highest risk of these reactions. [4] Present study was planned to evaluate the CDR, its type and severity with the drugs dispensed at IGGMC in 4 years of time duration.

Materials and Methods[top](#)

An observational, prospective study was conducted from 1st June 2005 to 31st May 2009 in the Dermatology OPD at IGGMC and H, Nagpur. The study was approved by the Institutional Ethics Committee. All the suspected patients of cutaneous drug reaction in the hospital were referred to dermatology OPD and diagnosis was made by dermatologist after obtaining detailed drug history and physical examination. The data was collected by using spontaneous ADR reporting system. [5]

The data was recorded as per ADR form obtained from Central Drugs Standard Control Organization (CDSCO) website, www.cdsc0.nic.in. The patient's initials, age, gender, type of cutaneous ADR, history of disease, categorization of ADR as serious according to WHO criteria, starting date of ADR, suspected drug causing ADR etc. were noted. The data was analyzed and causality was done by using WHO causality scale and consulting respective physician and dermatologist. [6]

Results[top](#)

[Table 1] shows age and gender distribution of patients. Total 560 males and 312 females developed CDRs and were mostly in age group of 21- 40 yrs.

Age	Male	Female	Total	%
0-10	10	25	35	2.3
11-20	82	42	124	13.2
21-30	211	109	320	31.3
31-40	114	55	169	21.1
41-50	95	47	142	14.7
51-60	28	13	41	4.8
61-70	14	7	21	2.4
Total	560	312	872	100

Table 1: Age and gender wise distribution of patients reporting CDRs

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[Table 2] shows the percentage of CDRs among the total ADRs collected in IGGMC and H during the study period. Total 2639 ADRs were reported, out of which 872 CDRs were contributing 33.04% of ADRs.

Period	Total number of ADRs	Number of CDRs	% of CDRs
Jan 01-May 05	927	222	23.95
Jan 06-May 07	342	205	60.00
Jan 07-May 08	976	243	24.89
Jan 08-May 09	404	271	67.08
Total	2639	872	33.04

Table 2: Percentage of cutaneous ADRs reported from 1st June 05 to 31st May 09

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[Table 3] shows that the most common CDRs reported were maculopapular rash (37.73%) and fixed drug eruptions (17.2%) followed by urticaria (14.56%), pruritus (9.06 %), flaring of tinea (Tinea incognito) (6.54%) and acneiform eruptions (5.62%). 17 CDRs reported as serious, as per WHO definition, were anaphylaxis with angioedema (6), Steven Johnson Syndrome (10), 2 being fatal and dapsone sensitivity syndrome (1). [6]

Cutaneous ADR	Frequency	%
Maculopapular rash	141	16.19
Fixed drug eruptions	130	15.02
Urticaria	127	14.56
Pruritus	82	9.41
Flaring of tinea	43	4.93
Acneiform eruptions	40	4.59
Stevens Johnson Syndrome	10	1.15
Myocarditis	1	0.11
Anaphylaxis	6	0.69
Angioedema	6	0.69
Dapsone sensitivity syndrome	1	0.11
Other	25	2.87
Total	872	100

Table 3: Classification of cutaneous ADR

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[Table 4] shows drugs causing serious drug reactions in the form of Anaphylaxis with angioedema (Ampicillin 5 and ibuprofen 1), Steven Johnson syndrome (Cotrimoxazole 5, ciprofloxacin, ofloxacin, chloroquine, cephalexine and paracetamol 1 each) and dapsone sensitivity syndrome (1). Out of these serious reactions 2 cases of SJS were fatal and others had to be hospitalized for further treatment.

Drugs	Frequency	%
Ampicillin	5	5.88
Ibuprofen	1	1.15
Cotrimoxazole	5	5.88
Ciprofloxacin	1	1.15
Ofloxacin	1	1.15
Chloroquine	1	1.15
Cephalexine	1	1.15
Paracetamol	1	1.15
Dapsone	1	1.15
Total	17	1.95

Table 4: Drugs causing serious ADR

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[Table 5] shows that most of the CDRs were attributed to antimicrobials (55.5%). The second most common offending drug group was NSAIDs (18.56%). Steroids- oral and topical (12.61%) and other drugs contributed to the extent of 13.3%.

Drug groups	ADR	%
Antimicrobials	484	55.50
NSAIDs	142	16.29
Steroids	111	12.73
Other	135	15.48
Total	872	100

Table 5: Common groups of drugs causing CDRs

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[Table 6] shows the top ten drugs causing CDRs. Cotrimoxazole (20.41%) was found to be the most common offending drug. Others were topical steroids- betamethasone (9.06%), ibuprofen (7.91%), ampicillin (6.54%), diclofenac sodium (4.7%), iron dextran (3.44%), ciprofloxacin (3.33%), isoniazide (3.21%), chloroquine (2.41%), and metronidazole (2.06%)

Drugs	CDR	%
Cotrimoxazole	172	19.73
Betamethasone	81	9.30
Ibuprofen	65	7.45
Ampicillin	54	6.19
Diclofenac	43	4.93
Iron dextran	29	3.33
Ciprofloxacin	27	3.10
Isoniazide	26	2.99
Chloroquine	21	2.41
Metronidazole	20	2.30
Total	872	100

Table 6: Top ten drugs causing cutaneous ADR

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[Figure 1] shows that total 95 CDRs were due to self medications and mostly in the form of acneiform eruption (32-Betamethasone 30 and clobetasol 2) and tinea incognito (57-Betamethasone 46 and clobetasol 11).

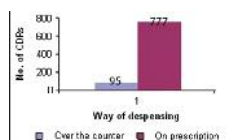


Figure 1: No. of CDRs according to the way of dispensed medication

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[Figure 2] shows that causality analysis was done by using WHO assessment scale and it was found to have 580 certain, 260 probable and 32 possible CDRs.

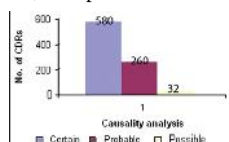


Figure 2: Causality analysis using WHO assessment scale

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Discussion



In the present study we found that CDRs, was one of the most common types of ADRs found in the IGGMC and H, which contributes 33.04% of total ADRs. Various studies suggest that the contribution of CDRs is 2-40% in total adverse drug reactions. [\[7\],\[8\],\[9\]](#)

In the present study the morphological varieties of CDRs commonly reported were maculopapular rash and fixed drug eruptions followed by urticaria, pruritus, tinea incognito (flaring of tinea) and acneiform eruptions. Acneiform eruptions and tinea incognito were found to be mostly due to self medication (89) of topical steroids and repeated use of older prescriptions [\[Figure 1\]](#). Various studies and literatures have already concluded that maculopapular rash is the most common CDRs. [\[7\]](#)

The commonest offending drug group for CDRs was antimicrobials (55.5%). The second most common offending drug group being NSAIDs (18.56%) while steroids was third most common group (12.61%).

A study performed by Ghosh, *et al.* in Manipal found that antimicrobials (30%) were the most common group causing CDRs. [\[7\]](#) Another study done by Jhaj, *et al.*, found that maculopapular rashes (50%) and urticaria (21.5%) were common morphological CDRs and antimicrobials (56.9%) were the most common culprits. [\[8\]](#) Also Noel, *et al.*, found that maculopapular rash was (35%) the most common CDR in the hospitalized patients. [\[9\]](#) Chatterjee, *et al.*, in their study also found that antimicrobials were topmost in causation of CDRs (34.10%) followed by anticonvulsants (32.88%) and NSAIDs (21.51%). [\[3\]](#) Results of our study were comparably similar to above mentioned studies.

The common offending drugs causing CDRs are mentioned in the [\[Table 6\]](#). Cotrimoxazole (20.41%) showed highest CDRs followed by betamethasone 9.06%, ibuprofen (7.91%), ampicillin (6.54%), diclofenac sodium (4.7%), and iron dextran (3.44%). This list corresponds with the results of some studies done in India. [\[10\]](#) A study performed by Pundukadan, *et al.*, also found that the most common drug causing CDRs was cotimoxazole (22.2%). [\[11\]](#)

In our study most of the offending drugs were taken orally (682) or topically (143) and least by parenteral route (47).

In our study causality analysis was done by using WHO assessment scale and it was found to have 580 certain, 260 probable and 32 possible CDRs. Causality analysis was done completely by consulting the treating physician, dermatologist and thorough literature review. Challenge and Re-challenge was not in any case [\[Figure 2\]](#).

Most of the ADRs were avoidable and treatable and subsided after symptomatic treatment. 17 CDRs were found to be serious, 10 of Steven Johnson Syndrome (SJS) (2 were fatal), 6 of anaphylaxis with angioedema and 1 case of dapsone sensitivity syndrome which required immediate medical attention and hospitalization. In the study of 464 case series reported by Kauppinen K. found that 4% patients had SJS. [\[12\]](#)

There might be many causes for the higher incidence of ADRs to a particular drug in this study. Limited list of drugs are supplied for dispensing in Govt. hospitals like others. Patient visiting our hospital OPDs belong to low socioeconomic class and thus can not afford to buy medicines from private pharmacies. So the patients on a treatment seem to develop ADR with the medication available in this hospital. Hence this data may not be truly reflective of the whole population which may be exposed to a large variety of drug formulations. Secondly, due to poverty, patients are likely to prefer older prescriptions for self medicating a particular ailment rather than revising the physician. As such total 95 ADRs due to self medication were found consisting of acneiform eruptions (32-Betamethasone 30 and clobetasol 2) and tinea incognito (57-Betamethasone 46 and clobetasol 11). In our study most patients themselves used steroid ointment to treat acne and tinea cruris causing CDRs.

As this study was based on spontaneous ADR reporting, under reporting, which is the major limitation of spontaneous method of ADR reporting, cannot be denied. Despite the limitations and variations in the study, this data may be important for the clinicians to report the ADRs and avoid irrational drug use. This data also reveals the dangers of self medication of drugs over the counter, which is generally thought to be harmless stuff.

Acknowledgement



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What is new?

CDRs evolved as most common cause of ADR around 33.04%. Topical and oral steroids are the third common cause for CDR followed by antimicrobials and NSAIDs. It is also important to evaluate safety in OTC drugs and in preparations like ointment and creams.

Figures

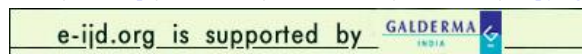
[\[Figure 1\]](#), [\[Figure 2\]](#)

Tables

[\[Table 1\]](#), [\[Table 2\]](#), [\[Table 3\]](#), [\[Table 4\]](#), [\[Table 5\]](#), [\[Table 6\]](#)

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