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Research Article

A prospective study on adverse drug reactions in outpatients and inpatients of medicine department in a tertiary care hospital

Harsha Ramakrishnaiah[1]*, Vasundara Krishnaiah[2], H. P. Pundarikaksha[2], Vedavathi Ramakrishna[3]

[1]Department of Pharmacology, The Oxford Medical College Hospital and Research Center, Bangalore, Karnataka, India, [2]Department of Pharmacology, Kempegowda Institute of Medical Sciences, Bangalore, Karnataka, India, [3]Department of Medicine, Kempegowda Institute of Medical Sciences, Bangalore, Karnataka, India

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***Correspondence to:**
Dr. Harsha Ramakrishnaiah,
Email: harsha.ramakrishnaiah@gmail.com

ABSTRACT

Background: No pharmacotherapeutic agent is completely free from noxious and unintended effects and thus adverse drug reactions (ADRs) are inevitable consequences of drug therapy. Incidence of ADRs in Indian population ranges between 1.8% and 25.1%. However, ADR reporting in India is inadequate. Developing awareness inpatients and healthcare professionals (HCPs) will help in reducing the ADRs, its suffering and socioeconomic impact. Hence, the present study of ADR monitoring in the outpatients and inpatients of the medicine department in a tertiary care hospital is undertaken. The main objective of this study was to assess the ADR reporting patterns in outpatient and inpatient of medicine department. The study was also aimed to assess the causality, severity, and preventability of these ADRs and comparison between spontaneous reporting by HCP and patient self-reporting of suspected ADRs.

Methods: This study was a prospective observational study conducted in 111 consecutive patients who experienced ADRs in the department of medicine. The study plan included analysis and assessment of the clinical pattern, spectrum of ADRs reported based on causality, severity, preventability factors. The impact of ADRs on emotional, occupational, and social life of patients was evaluated. The assessments were compared between patient reporting and HCP reporting of ADRs.

Results: The clinical spectrum of ADRs ranged from the more common mild reactions such as skin rashes, itching, nausea, and vomiting to moderately severe reactions prolonging the hospital stay. The predominant causative drugs were antimicrobials, antiretrovirals, non-steroidal anti-inflammatory drugs and antihypertensives. The majority of ADRs were probable in causality assessment, moderate in severity and probably preventable. Comparison of ADR reporting between patient and HCP revealed that ADRs reported by patient's been less in incidence, similar in qualitative analysis to HCP with very elaborative narration and highlighted emotional and occupational impact due to ADRs than HCP reports.

Conclusion: A wide range of ADRs are possible in medicine department. Adequate awareness of ADR reporting and precautions, while prescribing drugs are essential. Including patients as additional reporters of suspected ADR may add to the benefit of pharmacovigilance.

Keywords: Adverse drug reactions, Patient self-reporting, Pharmacovigilance

INTRODUCTION

Adverse drug reaction (ADR) is a dominant ubiquitous and preventable public health issue with its incidence in Indian population ranging between 1.8% and 25.1%, with 8% resulting in hospitalization. It is an inevitable consequence of drug therapy, as no pharmacotherapeutic agent is completely safe and more than 50% of approved drugs are associated with some type of adverse effects that are not detected prior to their approval for clinical use.[1,2] Even though ADRs are implicated as seventh common cause of death and up to 57% of them being unrecognized by attending physicians, the data remain limited and inconsistent.[3,4]

Owing to various factors such as age, gender, ethnicity, genetic factors, polypharmacy, drug interactions, multiple and inter-current diseases, increased length of hospital stay, dietary and environmental factors, the occurrence

of ADRs in internal medicine department is reported to be higher and contributes to the burden of drug-related patient morbidity and mortality adding to the cost of patient healthcare. The main drawback of a common ADR reporting method - spontaneous reporting system by health care professionals (HCP) is under-reporting and selective reporting, which leads to a false conclusion about drug risk. Therefore, including patients as reporters of ADR may increase its early detection and reporting and provide useful added source of information as patients are found to perceive ADRs more rapidly and clearly, than HCP.[5-8]

ADR reporting and monitoring activities are of vital importance for patient safety, which can generate valid data regarding causality association, preventability and severity of ADRs in the human population. The objective of this prospective observational study was to assess the inpatient and outpatient ADR reporting patterns in medicine department. Evaluation of the causality, severity, and preventability of reported ADRs was also carried out. The study also aimed to compare direct ADR reporting by patients versus ADR reporting by healthcare professionals.

METHODS

Totally, 111 consecutive outpatient and inpatient patients of both gender admitted to medicine department of a tertiary care, teaching hospital, and research center, with suspected ADRs and willingness to give written informed consent and available for follow-up were included in the 18 months study between January 2012 and June 2013. Patients with drug reaction due to deliberate or unintentional over dosage, alternate medicine systems such as Ayurveda, Homeopathy, and Unani, prescribing and dispensing error reactions due to blood and blood products, mentally retarded or unconscious patients were excluded from the study.

Study procedure

Data of spontaneously reported ADRs for each patient by HCP were collected and a detailed history including drug, patient demographics, family, past medical history, and history of previous drug allergy was documented, after discussion with the treating physician. Data pattern, extent, severity, duration of the reactions, predisposing pathological factors, other organ involvement as a part of the drug reaction were clinically scrutinized interpreted and analyzed for their clinical types, and causative drugs. The comparison of the spontaneous reporting between HCP and patients, social, emotional, occupational impact factors, and ADRs narrative elaboration scores for root cause of the reactions was assessed by WHO-UMC and Naranjo's causality assessment scale, severity of ADR using Modified Hartwig scale and Modified Schumock and Thornton scale was adopted to assess preventability. Patients were motivated to report the suspected ADRs to pharmacovigilance unit through regular awareness.

Statistical analysis

The data were analyzed using descriptive statistics namely mean and standard deviation for quantitative variables and the association between two different discrete variables was assessed using Chi-square test. SPSS V13 statistical software was used to generate graphs and tables wherever necessary. All multiple responses are reported in terms of percentages and total of such response will be greater than sample size. The chi-square test was implemented to analyze the association between two discrete variables, mean, and standard deviation to assess quantitative variables from the pooled data.

RESULTS

All patients enrolled in this study fulfilled the inclusion criteria and were completely compliant with the study procedures and instructions. A total of 195 ADRs were reported from 111 patients. The mean age was 40.77±15.64 years (41.96±16.52 for males and 38.76±14.01 for females) the mean age difference between the gender was not statistically significant ($p>0.05$), the eldest being 95 years and the youngest patient being 18 years of age. Most of the patients (n=40) were in the age group of 41-60 years. One patient was above 80 years in age, 13 patients were aged between 61 and 80 years, 33 patients were aged between 26 and 40 years, and 24 patients were aged between 18 and 25 years. Higher incidence of ADRs was observed in male patients (n=70) when compared to females (n=41).

Modified Kuppuswamy scale[9] was considered to evaluate the socioeconomic status. Most of the patients (40%) were from lower middle followed by 23% from upper lower, 21% from the upper class, and 17% were from upper middle socioeconomic status. The reported ADRs in the study patients are depicted in Table 1. There was no statistically significant difference in ADR experiences between genders. Figure 1 describes the organ systems involved in ADRs with gender distribution. The most common organ system affected was skin, accounting for 43% of total ADRs.

The suspected therapeutic class of drugs causing ADRs was elaborated in Table 2. It was noted that 46% of ADRs were caused due to antimicrobials and 5% due to anti-epileptics. Oral hypoglycemic agents, an opioid analgesic, anxiolytics, and antidepressant were the cause for ADRs in 1% of patients. There was no statistically significant difference in ADR caused by suspected therapeutic class of drugs between genders. The list of suspected ADRs and its causative agents are listed in Table 3.

Among all the reported ADRs with respect to WHO causality assessment, 53% were considered probable in causality, 44% were possible, and 3% were evaluated as being certain in causality (Figure 2). According to Naranjo's probability scale, 52% of ADR were evaluated as being probable, 45% as being possible, and 3% of ADRs belonged to the certain category. Assessment

Table 1: Types of ADRs reported in study patients.

ADR	Gender n (%) (n=111)		
	Male	Female	Total*
Skin rash	26 (22)	17 (23)	43 (22)
Pruritus	25 (21)	16 (21)	41 (21)
Nausea and vomiting	7 (6)	7 (9)	14 (7)
Headache	1 (1)	1 (1)	2 (1)
Abdominal discomfort	4 (3)	4 (5)	8 (4)
Diarrhea	2 (2)	2 (3)	4 (2)
Constipation	1 (1)	0 (0)	1 (1)
Sleep disturbances	1 (1)	0 (0)	1 (1)
Obesity	0 (0)	3 (4)	3 (2)
Lab abnormalities	2 (2)	3 (4)	5 (3)
Breathlessness	8 (7)	1 (1)	9 (5)
Giddiness	11 (9)	2 (3)	13 (7)
Swelling of legs	4 (3)	4 (5)	8 (40)
Myalgia	2 (2)	2 (3)	4 (2)
Tremors of hands	2 (2)	2 (3)	4 (2)
Discoloration of sclera	2 (2)	2 (3)	4 (2)
Others	22 (18)	9 (12)	31 (16)
Total	120 (100)	75 (10)	195 (100)

*Complaints overlap and total percentage does not add up to 100%. ADR: Adverse drug reaction

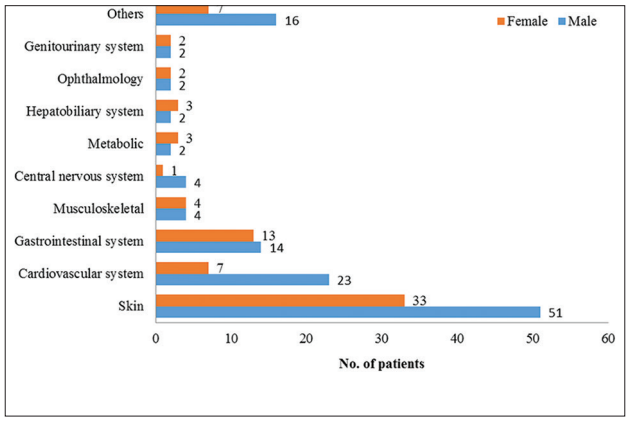

Figure 1: Organ system affected by adverse drug reactions in the study patients.

based on modified Hartwig scale showed that 59% ADRs were categorized as moderately severe, 37% were of mild severity and 4% of cases were evaluated as severe (Figure 3). No fatalities due to ADR were recorded in the study. Evaluation based on modified Schumock and Thornton criteria on the preventability of suspected ADR revealed that 90% of ADRs were probably preventable, 8% were preventable, and only 2% of reported ADRs were not preventable.

Of 111 patients, the majority (71%) of the ADRs were reported by HCPs and 29% (n=32) by patients. Among the HCP fraternity majority of ADRs were reported by

Table 2: Therapeutic class of drugs is causing ADRs in study patients.

Class of drugs causing ADR	Gender n (%) n=111		
	Male	Female	Total
Antimicrobials	34 (49)	17 (41)	51 (46)
Antiretroviral agents	8 (11)	2 (5)	10 (9)
NSAIDS	3 (4)	5 (12)	8 (7)
Antihypertensives and diuretics	3 (4)	1 (2)	4 (4)
Oral hypoglycemic agents	1 (1)	0 (0)	1 (1)
Antiepileptics	3 (4)	3 (7)	6 (5)
Corticosteroids	2 (3)	3 (7)	5 (4)
Bronchodilators	1 (1)	1 (2)	2 (2)
Opioid analgesics	1 (1)	0 (0)	1 (1)
Hypolipidemic agents	0 (0)	2 (5)	2 (2)
Antiemetics	1 (1)	1 (2)	2 (2)
Anticancer agents	1 (1)	1 (2)	2 (2)
Antihistaminics	2 (3)	0 (0)	2 (2)
Anticholinergics	2 (3)	0 (0)	2 (2)
Anxiolytics	1 (1)	0 (0)	1 (1)
Antipsychotics	0 (0)	1 (2)	1 (1)
Antidepressants	2 (3)	0 (0)	2 (2)
Hematinics	1 (1)	1 (2)	2 (2)
Vitamin A analogues	2 (3)	0 (0)	2 (2)
Others*	2 (3)	2 (5)	4 (4)
Total	70 (100)	41 (100)	111 (100)

*Others included tamsulosin, chloroquine, and calcium carbonate. ADR: Adverse drug reactions, NSAIDS: Non-steroidal anti-inflammatory drugs

postgraduate students. Comparison of the socioeconomic status of cases reported by HCPs and patient direct reporting revealed a different pattern. Among the ADRs reported by HCP, 44% were from lower middle class, 30% were from upper lower class, 15% were from upper middle and 10% upper class. Whereas among patient direct reporting 47% were from the upper class, 22% from the lower middle, 22% from upper middle, and 3% from upper lower socioeconomic status.

Comparison of presenting complaint between patient and HCP showed no statistically significant difference (p=0.4305), except for gastrointestinal side effects such as abdominal discomfort, epigastric pain, diarrhea was reported more by patients than HCP (p=0.0003) (Table 4). Comparison of suspected class of medication causing ADR between HCP and patient direct reporting revealed that HCPs reported 51% ADRs due to antimicrobials as compared to 34% (n=11) inpatient reporting. Similarly, HCPs reported 13% (11) of ADRs by antiretrovirals as compared to none inpatient group (p=0.03). Statistically, a significant difference between ADRs reported by HCP and patient was not observed in other class of medication causing ADRs.

Table 3: List of ADRs and its causative agents.

ADRs	Causative drugs
Skin rashes and itching	Ceftriaxone (9), azithromycin (4), amoxicillin (5), gentamicin (1), streptomycin (4), isoniazid (1), rifampicin (2), pyrazinamide (2), metronidazole (1), zidovudine (2), lamivudine (1), nevirapine (2), dapsone (1), paracetamol (2), diclofenac (3), ibuprofen (2), aspirin (1), amlodipine (1), carbamazepine (1), phenytoin (1), prednisolone (1), salbutamol (1), calcium carbonate (1), duloxetine (1), tamsulosin (1), risperidone (1), chloroquine (1), cefuroxime (1)
Blackish palms	Cyclophosphamide (1)
Nausea and vomiting	Isoniazid (1), zidovudine (1), aztreonam (1), phenytoin (1), Chlordiazepoxide (1), alprazolam (1), tramadol (1)
Diarrhea	Domperidone (1)
Constipation	Methyl prednisolone (1)
Pain abdomen	Cefixime (2), amoxicillin (3), aspirin (1), ceftriaxone (3), Rifampicin (2), metronidazole (1), oral ferrous sulfate (2)
Headache	Duloxetine (1), isotretinoin (1), ofloxacin (1)
Insomnia	Tamsulosin (1)
Tremors	Salbutamol (1), terbutaline (1)
Breathlessness	Zidovudine (5), ibuprofen (1)
Giddiness	Ceftriaxone (3), gentamicin (1), metformin (1), diethyl Carbamazine (1), duloxetine (1)
Myalgia	Isotretinoin (1), atorvastatin (1), rosuvastatin (1), ofloxacin (1)
Weight gain (obesity)	Prednisolone (3)
Asymptomatic abnormality in LFT (reversible)	Isoniazid (2), rifampicin (3)
Pancytopenia	Sodium valproate (1)
Anemia	Zidovudine (7)
Peripheral neuropathy	Lamivudine (2)
Delirium	Atropine (1)
Extrapyramidal symptoms	Metoclopramide (1)
Dryness of mouth	Atropine, dicyclomine, chlorpheniramine, pheniramine

ADR: Adverse drug reactions, LFT: Liver function test

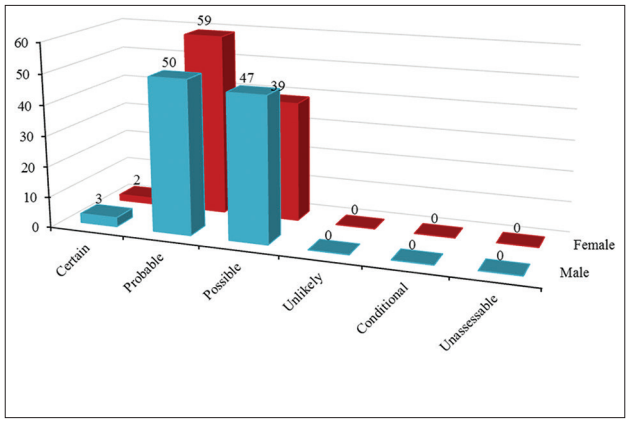

Figure 2: Causality assessment of reported adverse drug reactions by WHO probability scale.

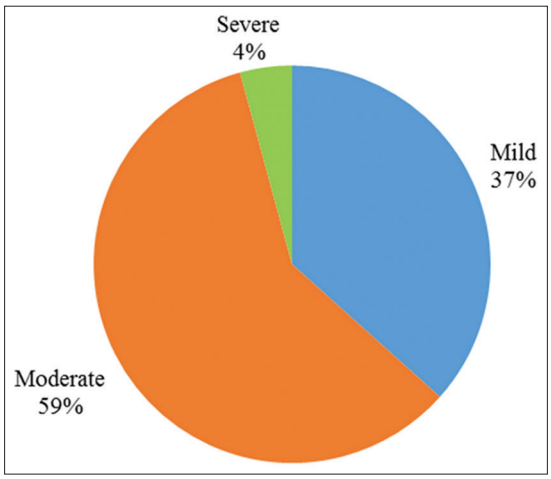

Figure 3: Severity of the reported adverse drug reactions in study patients.

Comparison of causality assessment between HCP and patient reports revealed that 46% of ADR reported by HCPs were probable as compared to 72% of patient reporting. Possible causality was assessed in 54% (n=43) of HCP reports whereas only 19% (n=6) of reports by the patient were assessed as possible. About 9% (n=3) of reports from patient were assessed as certain versus no reports from HCP

Table 4: Comparison of reported ADRs among HCPs and patients.

ADR	n (%)		p-value
	HCP	Patient	
Skin rash	35 (23)	8 (18)	0.4305
Itching	33 (22)	8 (18)	0.5421
Nausea and vomiting	13 (9)	1 (2)	0.142
Headache	2 (1)	0 (0)	0.4326
Abdominal discomfort	2 (1)	6 (13)	0.0003
Diarrhea	1 (1)	3 (7)	0.01276
Constipation	0 (0)	1 (2)	0.06719
Sleep disturbance	1 (1)	0 (0)	0.5829
Obesity	3 (2)	0 (0)	0.339
Lab abnormalities	5 (3)	0 (0)	0.2151
Breathlessness	8 (5)	1 (2)	0.383
Giddiness	11 (7)	2 (4)	0.4956
Swelling of legs	8 (4)	2 (4)	0.8126
Myalgia	4 (2)	2 (4)	0.5447
Tremors of hands	4 (2)	2 (4)	0.5447
Yellow sclera	4 (2)	2 (4)	0.5447
Others	16 (12)	7 (17)	0.3725
Total	150 (100)	45 (100)	

ADR: Adverse drug reactions, HCP: Healthcare professionals

due to plausible time relationship to drug intake, definitive pharmacologically recognized phenomenon with accidental re-challenge and recovery from drug de-challenge. A statistically significant difference in WHO causality assessment was observed between HCP and patient ADR reporting ($p<0.001$) with patient reporting more of certain and probable category. The Naranjo's probability scale based comparison of causality assessment of ADRs showed that 56% of reports by HCP were assessed as possible versus 19% reports by patient, and 44% of reports from HCP were assessed as probable versus 72% reports by patient. About 9% of reports from patients were assessed as certain, and no reports from HCP were certain. The severity of ADRs reported by HCP and patient compared using modified Hartwig severity scale indicated that 16% of ADRs reported by HCP and 88% ADRs reported by patients were of mild severity due to better perception. Moderately severe ADR reports by HCP were 78% in comparison to 9% by patients. Modified Schumock and Thornton preventability scale assessment revealed that, 92% of HCP and 84% of patient reporting were probably preventable, and 5% of HCP and 16% of patient reporting were definitely preventable.

Of the ADRs reported by patients, 50% were very elaborative, 34% had moderate narratives, 16% were with scanty narratives, and no reports were non-narrative. Of the ADRs reported by HCPs 1% were very elaborative, 3% had moderate narratives, 48% were with scanty narratives, and 48% reports were non-narrative. Only 9% of HCP reported ADR conveyed social impact in comparison to 22% reported by patients, which included restriction of normal routine activities due to muscle and joint pain, visual defects, confusion, depression. Occupational impact like unable to work due to headache, nausea, vomiting, sleep disturbances were reported by 44% of patients as compared to only 16% by HCP report with a statistically significant difference ($p=0.002$). Emotional impact like delirium and confusion was reported due to atropine. Similarly, depression and disturbed thoughts were reported due to prednisolone, anxiousness due to ciprofloxacin and ofloxacin, and low mood and confusion due to chlordiazepoxide. Thirty-one percentage of patient reporting showed a clear emotional impact as compared to only 13% by HCP report, which was statistically significant ($p=0.02097$).

DISCUSSION

The present study revealed the pattern of ADRs reported in medicine department. The causality, severity, and preventability of the ADRs reported by patient and HCP were assessed and compared. The social, emotional, and occupational impact of ADR in the patients' life were evaluated. All patients satisfied the inclusion and exclusion criteria. They were also compliant with the study protocol and guidelines.

Of the 111 patients included in the study, 36% were in the age group of 41-60 years. Similar results were recorded in other studies, which elaborated that increased usage of medicines increased the incidence of diseases such as diabetes and hypertension.[2] Male patients were more predisposed to ADRs[2,10,11] and a similar pattern of gender distribution was evident in the present study. Based on modified Kuppuswamy Scale, none of the ADRs were reported from the lower class indicating a probable lack of awareness of ADR reporting in this group.

Skin was the chief organ system affected with most common complaints of skin rashes, which was also observed in various previous studies.[12] Many previous studies including the present study have revealed that antimicrobials are the majority of ADR-causing drugs since they are the most commonly prescribed drugs.[3,13-16] Findings documented in the present study were consistent with the previous research, which revealed that the major antimicrobial drug causing ADR was ceftriaxone, antiretroviral drug was zidovudine, non-steroidal anti-inflammatory drugs (NSAIDs) was diclofenac, antiepileptic drugs was phenytoin sodium and carbamazepine, antihypertensive drug was amlodipine as they were the most common drugs used in their class.[17-25]

The causality assessment of reported ADRs by WHO probability scale revealed that the majority of the reported ADRs were probable, which is in accordance with the previous studies.[26,27] Naranjo's probability scale also showed that most of the (52%) ADRs were probable, which is consistent with past studies.[28-30] Evaluation modified

Hartwig scale also revealed that the majority of ADRs were moderately severe, which was consistent with other studies.[31,32] The preventability of suspected ADRs assessed by modified Schumock and Thornton criteria showed that 90% of ADRs were probably preventable, which is in accordance with previous study.[31]

In contrast to the elaborate description of ADR by patient direct reporting, the majority of ADR description reported by HCP was inadequate. Most of the patient direct reporting emphasized on emotional and occupational impact of ADR in their life than the ADRs reported by HCP.[32] Majority of the ADRs were reported by HCP was evident due to better knowledge of pharmacovigilance prevailing among HCP. Better awareness about ADR among upper socio-economic class patient self-reporting of ADR was observed to be higher in contrast to HCP reported ADR containing the majority of study patients from lower middle socioeconomic status. Limited number of patients enrolled in the study was a major limitation in this study along with the fewer frequency of ADR reported by patients. Motivational program and awareness of ADR could have been increased the reports by the patient. The denominator indicative of the total number of patients exposed to a particular drug, out of which how many developed ADR would have been more informative to calculate the incidence of ADR.

CONCLUSION

The clinical spectrum of ADRs reported from the Department of Medicine ranged from the more common mild reactions such as skin rashes, itching, nausea, and vomiting to moderately severe reactions prolonging the hospital stay of the patients. No fatalities due to ADR were reported. The predominant causative drugs were antimicrobials, antiretroviral agents, NSAIDs, and antihypertensive agents. The majority of ADRs were probable in causality assessment, moderate in severity and probably preventable. The majority of ADRs were reported by HCP as compared to patient direct reporting of ADR. Comparison of ADR reporting between HCP and patient revealed similarity in the qualitative analysis in terms of presenting complaints, drug causing pattern, and preventability of ADR. In contrast to HCP, patient reporting of ADR had very elaborative narration and highlighted more about emotional and occupational impact of ADR on patient's life.

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REFERENCES

1. Sriram S, Ghasemi A, Ramasamy R, Devi M, Balasubramanian R, Ravi TK, et al. Prevalence of adverse drug reactions at a private tertiary care hospital in south India. J Res Med Sci. 2011;16(1):16-25.
2. Rabbur RS, Emmerton L. An introduction to adverse drug reporting system in different countries. Int J Pharm Pract. 2005;13(1):91-100.
3. Padmaja U, Adhikari P, Pereira P. A prospective analysis of adverse drug reaction in a south Indian hospital. Online J Health Allied Sci. 2009;8(3):12.
4. Farcas A, Bojita M. Adverse drug reactions in clinical practice: a causality assessment of a case of drug-induced pancreatitis. J Gastrointestin Liver Dis. 2009;18(3):353-8.
5. International society of drug bulletin (ISBD). Berlin Declaration on Pharmacovigilance (ISBD Workshop). Berlin: ISBD EU; 2005.
6. Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385-96.
7. McGettigan P, Golden J, Conroy RM, Arthur N, Feely J. Reporting of adverse drug reactions by hospital doctors and the response to intervention. Br J Clin Pharmacol. 1997;44(1):98-100.
8. Hammond IW, Rich D. Consumers usurp spontaneous adverse event reporting in the United States. Pharmacoepidemiol Drug Saf. 2005;14:88-9.
9. Kumar N, Shekhar C, Kumar P, Kundu AS. Kuppuswamy's socioeconomic status scale-updating for 2007. Indian J Pediatr. 2007;74(12):1131-2.
10. Gupta R, Sheikh A, Strachan D, Anderson HR. Increasing hospital admissions for systemic allergic disorders in England: analysis of national admissions data. BMJ. 2003;327:1142-3.
11. Chawla S, Kalra BS, Dharmshaktu P, Sahni P. Adverse drug reaction monitoring in a tertiary care teaching hospital. J Pharmacol Pharmacother. 2011;2(3):196-8.
12. Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. Br J Clin Pharmacol. 2008;65(2):210-6.
13. Wester K, Jönsson AK, Spigset O, Druid H, Hägg S. Incidence of fatal adverse drug reactions: a population based study. Br J Clin Pharmacol. 2008;65:573-9.
14. Gor AP, Desai SV. Adverse drug reactions (adr) in the inpatients of medicine department of a rural tertiary care teaching hospital and influence of pharmacovigilance in reporting ADR. Indian J Pharmacol. 2008;40(1):37-40.
15. Vora MB, Trivedi HR, Shah BK, Tripathi CB. Adverse drug reactions in inpatients of internal medicine wards at a tertiary care hospital: a prospective cohort study. J Pharmacol Pharmacother. 2011;2(1):21-5.
16. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalized patients. Results of the harvard medical practice study II. N Engl J Med. 1991;324(6):377-84.
17. Kathiria JM, Sattigere BM, Desai PM, Patel SP. A study of adverse drug reactions in patients admitted to intensive care unit of a tertiary care teaching rural hospital. Int J Pharm Pharm Sci. 2013;5(1):160-3.
18. Sharma SK. Zidovudine-induced anaemia in HIV/AIDS. Indian J Med Res. 2010;132:359-61.
19. Vijendra R, Pundarikaksha HP, Gopal MG, Girish K, Vasundara K, Jyothi R. A prospective study of cutaneous adverse drug reaction in a tertiary care hospital. Natl J Basic Med Sci. 2013;3(1):44-51.
20. Shah SP, Desai MK, Dikshit RK. Analysis of cutaneous adverse drug reactions at a tertiary care hospital: a prospective study. Trop J Pharm Res. 2011;10(4):517-22.
21. Noel MV, Sushma M, Guido S. Cutaneous adverse drug reactions in hospitalized patients in a tertiary care center. Indian J Pharmacol. 2004;36(5):292-5.

22. Hussain MM, Girhepunje K, Pal R, Siddiqua SS. Incidence of adverse drug reactions in a tertiary care hospital: a systematic review and meta-analysis of prospective studies. Pharm Lettr. 2010;2(3):358-68.
23. Khurshid F, Aqil M, Alam MS, Kapur P, Pillai KK. Monitoring of adverse drug reactions associated with antihypertensive medicines at a university teaching hospital in New Delhi. Daru. 2012;20(1):34.
24. Aqil M, Imam F, Hussain A, Alam MS, Kapur P, Pillai KK. A pharmacovigilance study for monitoring adverse drug reactions with antihypertensive agents at a south Delhi hospital. Int J Pharm Pract. 2006;14:311-3.
25. Biston P, Mélot C, Degaute JP, Clement D, Quoidbach A. Prolonged antihypertensive effect of amlodipine: a prospective double-blind randomized study. Blood Press. 1999;8(1):43-8.
26. Acharya T, Mehta D, Shah H, Dave J. Pharmacovigilance study of adverse cutaneous drug reactions in a tertiary care hospital. Natl J Physiol Pharm Pharmacol. 2013;3:75-81.
27. Chatterjee S, Ghosh AP, Barbhuiya J, Dey SK. Adverse cutaneous drug reactions: a one year survey at a dermatology outpatient clinic of a tertiary care hospital. Indian J Pharmacol. 2006;38:429-31.
28. 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.
29. Polimeni G, Salvo F, Cutroneo P, Morreale I, Patrizio Caputi A. Adverse reactions induced by NSAIDs and antibacterials: analysis of spontaneous reports from the Sicilian regional database. Drug Saf. 2006;29(5):449-59.
30. Jha N, Bajracharya O, Namgyal T. Prevalence of adverse drug reactions with commonly prescribed drugs in different hospitals of Kathmandu valley. Kathmandu Univ Med J (KUMJ). 2007;5(4):504-10.
31. Palanisamy S, Kumaran KS, Rajasekaran A. A study on assessment, monitoring, and reporting of adverse drug reactions in Indian hospital. Asian J Pharm Clin Res. 2011;4(3):112-6.
32. Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A, Hannaford PC, et al. Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow card scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. Health Technol Assess. 2011;15(20):1-234.

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