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A SIX MONTH PROSPECTIVE-OBSERVATIONAL STUDY ASSESSING ADVERSE DRUG REACTION MONITORING METHODS AND REPORTING PATTERNS IN A NASCENT ADVERSE DRUG REACTION MONITORING CENTRE OF A TEACHING TERTIARY CARE HOSPITAL

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ABSTRACT
Pharmacovigilance is detection, assessment and prevention of adverse reactions or any other possible drug related problems. India joined WHO programme for adverse drug reaction monitoring and started pharmocovigilance programme of India which collects adverse drug reactions on spontaneous basis. Consequent upon the start of Pharmacovigilance Programme, after sensitization we started collecting ADRs. The total number of ADRs collected were 76 out of which Medicine department contributed 54(71.05%), Dermatology department 16 (21.05%) and Surgery department 4 (5.26%) over a period of six months. The number of spontaneous ADR reports received were 8 as compared to actively collected ADR reports which were 68, indicating under reporting of ADRs by spontaneous reporting. The active surveillance not only picked up ADRs equally from OPD and IPD but also those ADRs which required admission to the hospital indicating more holistic reporting with active surveillance. Overall the commonest class of drugs causing ADRs were Anticonvulsants (30)39.47%, Antimicrobials 20(26.31%), Anti psychotics 10(13.15%) and Antihypertensives 5(6.57%). Commonest serious ADRs causing class of drugs were Antimicrobials 17(85%), Anticonvulsants 12(40%) and Antihypertensives 1(20%) as compared to other studies. Our results indicated spontaneous reporting should not be relied upon as a large number of ADRs including serious ones are missed.

KEYWORDS: Pharmacovigilance, Adverse Drug Reaction, Monitoring, Surveillance.

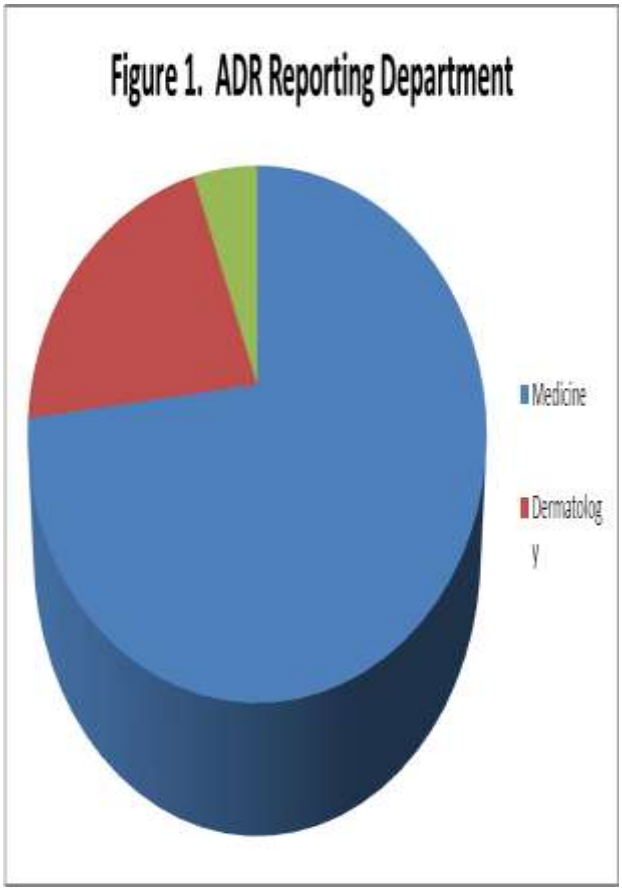
INTRODUCTION
A case report in Lancet suspecting a causal link between Phocomelia and Thalidomide heralded the birth of Pharmacovigilance in December 1961.[1] The aim of Pharmacovigilance is detection, assessment and prevention of adverse reactions or any other possible drug related problems.[2] India joined WHO programme for adverse drug reaction (ADR) monitoring in the year 1998.[3] Two different methods of ADR reporting are available.[4] Spontaneous reporting which is a passive surveillance with no active measures taken to look for adverse events other than the encouragement of the health care professionals and others to report safety concern and reporting is totally dependent upon the initiation and motivation of potential reporters.[5] Not able to motivate doctors to report ADRs and under reporting of ADRs spontaneously is common.[6] The other one is active surveillance, using phone structured interview, ward rounds and chart reviews or computer monitoring.[7] Presently Pharmacovigilance Programme of India(PVPI) is following spontaneous reporting for collection of data regarding drug safety on a standardized suspected adverse drug reaction reporting form.

MATERIAL METHODS
Government medical college Srinagar and associated hospitals was recently approved as an adverse drug monitoring center (AMC) under PVPI. Various initiatives including continuous Medical Education Programme by the Department of Pharmacology for paramedical staff, students and clinicians were held. Meetings were conducted with all Head of Departments to promote awareness and ensure spontaneous reporting of ADRs. It was also agreed upon that during the rounds they would ensure that ADRs are reported. Banners & posters were displayed at strategic sites ensuring maximum visibility. All monthly newsletters from PVPI were sent to various notice boards and head of the

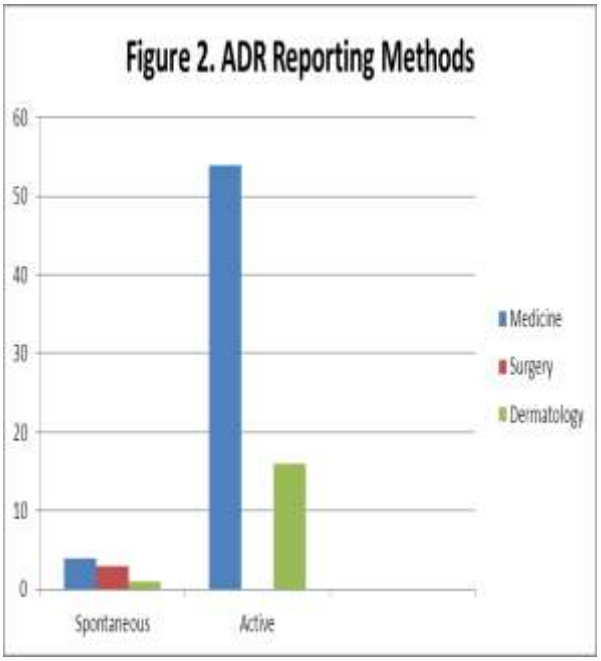
departments. ADR alerts received from time to time from PVPI were printed and sent to all head of departments with a plea for displaying them on notice boards for awareness of the concerned people. Moreover, personal interaction with the healthcare professionals was also done to ensure spontaneous reporting. Simultaneously we started active surveillance in those departments from which spontaneous reports were received by recruiting resident doctors. Senior residents and demonstrators also attended outpatient department (OPD) and wards for collecting ADRs. A standardized suspected adverse drug reaction reporting form was used for active surveillance and assessing seriousness of the ADR. Causality assessment was done in all by WHO UMC scale.[3]

RESULTS

Total no. of ADRs collected were 76 with Medicine contributing 54(71.05%), Dermatology 16 (21.05%) and Surgery 4 (5.26%) over a period of six months. (Fig. 1).



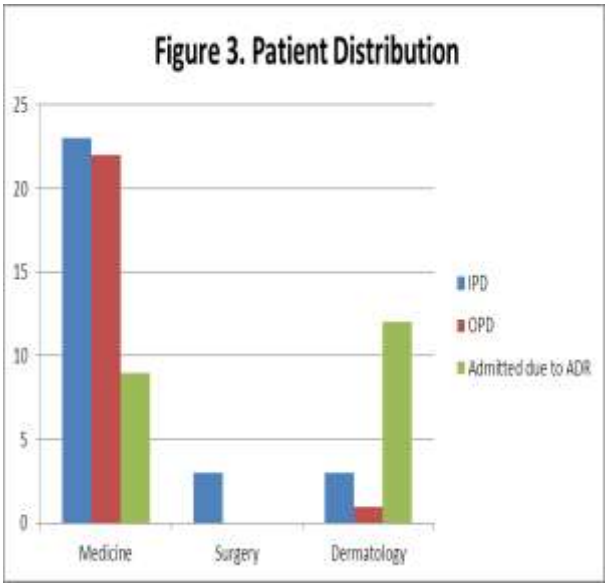
Spontaneously reported ADRs were 8 (10.52%) and 68 (89.47%) were collected by active surveillance. (Fig. 2).

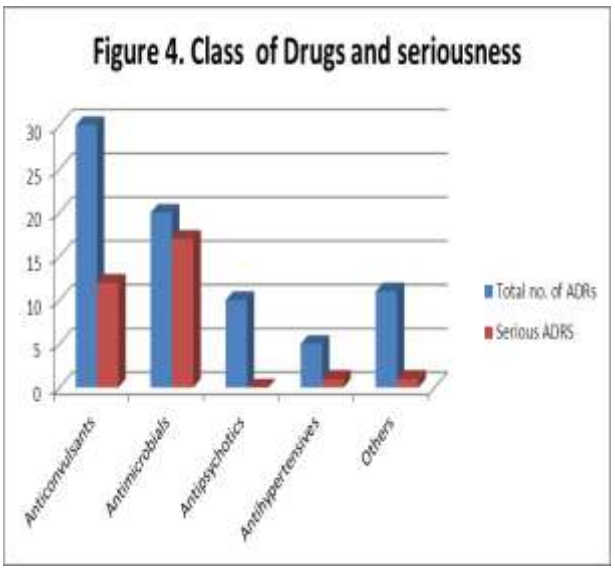


All the spontaneously reported ADRs were from inpatient department (IPD), 5(62.5%) reported by residents and 3(37.5%) by staff nurses. Medicine reported 4 ADRs caused by Ciprofloxacin, Levofloxacin, Moxifloxacin and Ceftriaxone. Surgery reported 3 ADRs caused by Ceftriaxone, Tinidizole and Prochlorperazine plus Paracetamol combination. Dermatology reported 1 ADR caused by Cefpodoxime. 4 ADRs were of serious nature which either prolonged hospital stay or required intervention. They were caused by 3 Quinolones and by combination of Paracetamol & Prochlorperazine. Causality assessment was received in 1 of the 8 cases.

Actively reported ADRs were 54 from Medicine, out of which IPD were 23(42.59%) and OPD were 22(40.74%) and those that got admitted for ADRs were 9(16.66%). Amongst 23 IPD ADRs, those caused by antimicrobials were 10(43.47%) (3 Quinolones, 2 Antiprotozoals, 2 Aminoglycosides and 3 serious ADRs caused by Meropenam, Vancomycin and Acyclovir). Those caused by anticonvulsants were 6(26.08%) (2 were serious ADRs caused by Phenytoin), those caused by Antihypertensives were 5(21.73%)(4 Calcium channel blockers causing one serious ADR and 1 Diuretic)and 2 ADRs caused by Metformin and Salbutamol . All 22 OPD ADRs were not serious and were caused by 10(45.45%) anticonvulsants 10(45.45%) antipsychotic antidepressants and 2(9.09%) antimicrobials. All 9 ADRs which required hospitalization were serious in nature and were caused by Levofloxacin 4, Phenytoin 2, Lamotrigine 2 and Methylprednisolone. Causality assessment showed possible 29 probable, 23 probable 1 likely and 1 definitive. From Dermatology 16 ADRs reports were collected ,out of which 3(18.75%) were IPD (Phenytoin 2, Lamotrigine 1), 1(6.25%) was OPD(Cefixime Ofloxacin combination)and those who got admitted for ADR were 12(75%)[5 Antiepileptic (Phenytoin 2, Phenobarbitone 1 and Lamotrigine 2),5

antimicrobials(Quinolones 2, Beta lactum 2, Sulfonamide 1), Piroxicam and combination of Ofloxacin and Ornidazole]. All ADRs collected were serious in nature. (Fig.3 & Fig.4).





DISCUSSION

Consequent upon the start of Pharmacovigilance Programme, the department of Pharmacology Government Medical College Srinagar and associated hospitals also started an ADR monitoring center. After post sensitization we started collecting ADRs. The total number of ADRs collected were 76 out of which Medicine department contributed the maximum, 54(71.05%) as was reported by others[8]. The number of spontaneous ADR reports received were 8 as compared to actively collected ADR reports which were 68 indicating under reporting of ADRs by spontaneous reporting.[9] There was also incompleteness of data, specifically causality assessment in spontaneous reports. All spontaneous reports were from IPD with residents reporting the maximum ADRs. All this indicates the need for sensitization programmes for senior doctors and paramedical staff to augment spontaneous reporting both from OPD as well as IPD.

The active surveillance not only picked up ADRs equally from OPD and IPD but also those ADRs which required admission to the hospital indicating more holistic reporting with active surveillance. Overall the commonest class of drugs causing ADRs were Anticonvulsants (30)39.47%, Antimicrobials 20(26.31%), Anti psychotics 10(13.15%), and Antihypertensives 5(6.57%). In other studies NSAIDs was most common group followed by Antimicrobials.[10]

Commonest serious ADRs causing class of drugs were Antimicrobials 17(85%), Anticonvulsants 12(40%) and Antihypertensives 1(20%) as compared to other studies.[11]

All Medicine OPD based ADRs were not serious with Anticonvulsants and Antipsychotics contributing equally. In Medicine IPD commonest group causing ADRs was Antimicrobials followed by Antiepileptics with serious ADRs caused by Phenytoin and in Dermatology all ADRs were of serious nature with Antiepileptics being commonest. This shows that Antiepileptics not only cause higher number of ADRs but serious ones also, with admissions more in Dermatology, underlining the need of specific monitoring of Antiepileptic drugs in Medicine IPD and Dermatology.

CONCLUSION

From our study we concluded that in implementing ADR monitoring cell, efforts should be made simultaneously for sensitization of spontaneous reporting as well as active surveillance. Only spontaneous reporting should not be relied upon as a large number of ADRs including serious ones are missed. Healthcare professionals should be made aware of the commonest class and groups of drugs causing ADRs as well as serious ADRs so the same can be picked up by active reporting till a time reaches when spontaneous reporting sensitization has reached to an optimal level.

However, the limitation of the study was that due to limited staff the study could not be carried out in all departments of the associated hospitals.

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