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Original Research Article

Pattern of adverse drug effects reported by patients being treated in a tertiary healthcare institution in North India: A retrospective observational study

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ABSTRACT

Introduction: Patient safety and well-being is favored by reporting adverse drug effects timely and precisely. Pharmacovigilance contributes to post-marketing surveillance and ensures that necessary changes may be done to the drug labels accordingly.
Objective: The study was aimed at observing, analyzing and reporting various adverse effects due to prescribed drug intake for patient conditions and diseases being treated at our tertiary healthcare institution.
Materials and Methods: Study was conducted at Dr. RPGMC, Kangra at Tanda, which is a multi-specialty tertiary healthcare hospital with 700 beds and an ADR monitoring Centre situated in the lap of western Himalayas in North India. Pattern of ADRs reported by the volunteers receiving drug therapy between January and December 2021 was assessed. Data pertaining to age, gender, drug intake, types of ADRs, treatment and outcome of the reactions was collected. Individual assessment was done for each patient. WHO scale was used for causality assessment. ADR profiling was carried out based on site, onset, organ system affected, duration, whether urgent referral was required or not and resolution of signs & symptoms. The data was analyzed using Microsoft excel 2019 and expressed as mean ± standard deviation & percentages.
Results: A total of 83 patients reported ADRs (adverse drug reactions). These were reported to IPC, Ghaziabad through our AMC (Adverse Drug Reaction Monitoring Centre) between 1st January 2021 and 31st December 2021. Gastro-intestinal system related adverse effects (35%) were most common followed by skin (22.9%) and CNS (12%) adverse effects. GI adverse effects included anorexia, dyspepsia, diarrhoea, oral ulcers, nausea, vomiting, weight-loss and raised liver function tests.
Conclusion: ADRs occur commonly but are often undetected. Even if detected they remain underreported as most of the health care professionals are unaware about pharmacovigilance. Therefore, mass sensitization and reward to those who report ADRs vigilantly is the need of the hour to promote patient safety.

1. Introduction

Adverse drug reactions (ADRs) are still one of the leading challenges in healthcare field which results in longer hospital stay and also indicates a socioeconomic burden to individual consumer as well as to the healthcare system.[1] Significant factors affecting ADRs occurrence includes patient related factors (Age, Gender, Maternity status and fetal development, allergy, race & ethnicity, body weight and fat distribution), drug related factors (polypharmacy,

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dose, frequency and route) and disease related factors (accompanied diseases) etc.[2]

It was observed that 5% of all hospital admissions were ADRs related admissions and nearly 10-20% of total hospital patients are developing ADRs.[3] ADRs may also result in the poor quality of life, increased physician visits and even death sometimes. Thus, they place a overburden on health care resources.[4]

Therefore, safety monitoring of medicines is an essential element of the healthcare system. Currently, WHO Collaborating Centre-UMC (Uppsala Monitoring Centre) in Sweden is looking medicine safety monitoring as a global centre.[5] In India, in the year 2010 the Ministry of Health and Family Welfare (MoHFW), initiated the nationwide Pharmacovigilance Programme of India (PvPI). Indian Pharmacopoeia Commission (IPC) under the MoHFW has been functioning as the National Coordination Centre (NCC) for PvPI from April 2011, since then rapid progress in exercising the culture of pharmacovigilance in the healthcare professionals is seen with aims to safeguard the health of the Indian population. It ensures the benefits of the use of medicine outweigh the risks associated with its use.[6] Voluntary reporting of adverse drug reactions by the health care professionals is the mainstay in generating data for onward submission to regulatory authorities. Under reporting is a major problem in this system. Hence, there is a need to increase health care professional's awareness in regards to detection, assessment, understanding and reporting of adverse drug reactions.

The Dr. R.P.G.M.C., Kangra at Tanda is a dedicated ADR monitoring Centre designated under PvPI and is working for the patient safety, in coordination with all the clinical and respective departments by detection, assessment, monitoring and reporting of the ADRs. Hence, this study aims to analyze the ADRs reported from our hospital so that physicians can anticipate the following ADRs while prescribing drugs to promote rationale usage of drugs.

2. Materials and Methods

This is a retrospective observational study done at adverse drug reaction monitoring Centre (AMC), Dr. R.P.G.M.C., Kangra at Tanda. The study was done on data of adverse drug effects collected at AMC following prescribed drug intake. The approval to analyze and publish data on adverse drug effects was granted by National Co-ordinating Centre, Pharmacovigilance Program of India (PvPI), Indian Pharmacopoeia Commission, Ghaziabad.

The data of the patients who reported adverse effects to pharmacovigilance associate at our AMC between January and December 2021 was included in the study. The identification of the patients was kept confidential and the data was also reported to NCC, PvPI. Adverse effects were recorded using preferred term (PT) & system organ classification, as under medical dictionary for regulatory activities (MedDRA)-a WHO medical terminology tool. The data was entered into Microsoft excel and analyzed using data analysis tool. The results were presented using appropriate Tables & Figures.

3. Results

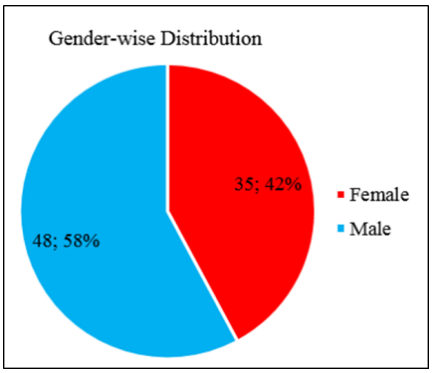

Fig. 1: Gender-wise distribution of patients reporting ADRs

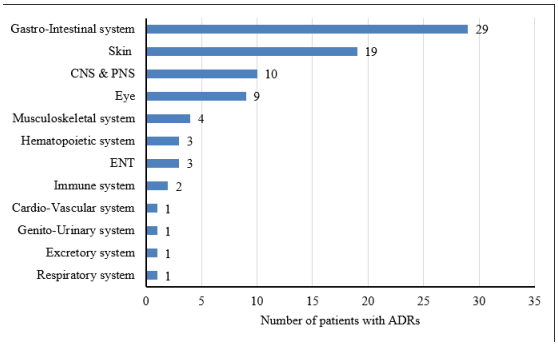

Fig. 2: Organ-system-wisedistribution of ADRs

Table 1: Age-group wise distribution of patients reporting ADRs.

Age-group	Male	Female	Total (83)
1-18 years	2	4	6 (7.23%)
19-40 years	18	15	33 (39.76%)
41-60 years	18	13	31 (37.35%)
61-80 years	9	3	12 (14.46%)
Above 80 years	1	0	1 (1.2%)

81 (98%) patients had non-serious adverse effects. 2 patients had serious adverse effects as per the standard criteria given by PvPI. A 62 years male on ART was receiving isoniazid for tuberculosis prophylaxis. He reported asthenia & dyspnoea and the drug was withdrawn. A 16 years old female patient reported hand & foot numbness along with drug induced anemia. She was receiving linezolid as part of her ATT and the dose was reduced following the adverse effect.

Table 2: Symptoms reported as ADRs

Symptoms	Number of patients having ADRs
Anorexia/Dyspepsia/Diarrhoea/ Oral ulcers/Nausea/ Vomiting/ Weight-loss/Raised LFTs	29 (35%)
Skin rash/Itching	19 (22.9%)
Anxiety/Dizziness/Headache/ Insomnia/ sedation/ Polydypsia/ Numbness	10 (12%)
Blurred vision/photophobia	9 (10.9%)
Asthenia/Body aches	4 (4.8%)
Anemia	3 (3.6%)
Tinnitus/vertigo	3 (3.6%)
Angioedema/Fever	2 (2.4%)
Palpitations	1 (1.2%)
Increased frequency of micturition	1 (1.2%)
Hyperuricemia	1 (1.2%)
Breathlessness	1 (1.2%)

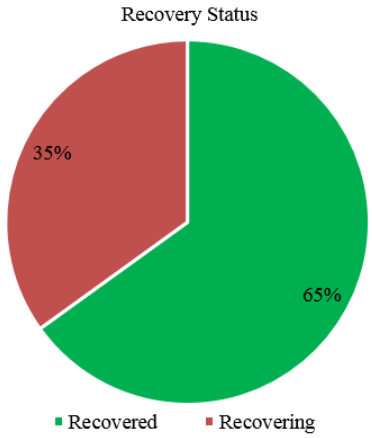

Fig. 3: Recovery status of patients who sustained drug adverse effects.

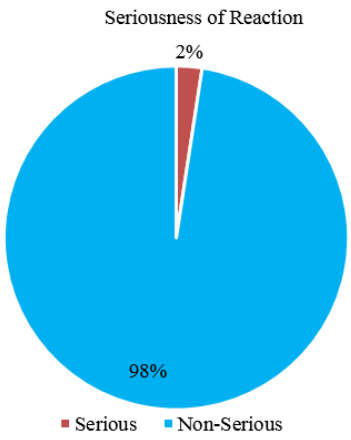

Fig. 4: Seriousness of reaction sustained as drug adverse effect.

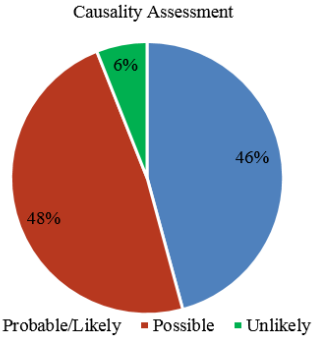

Fig. 5: WHO-Causality-wise distribution of ADRs.

A total of 83 patients reported ADRs at our Centre from January to December 2021. Most patients had mild adverse effects. 65% patients had recovered and 35% were recovering at their last follow-up.

4. Discussion

This was a retrospective descriptive observational study of adverse drug effects at our AMC in a tertiary health care institution of Northern India from January to December 2021.

A total of 83 adverse drug reactions were studied and reported to NCC, PvPI, Ghaziabad, India.

In our study out of total 83 patients who reported ADRs, 48 (58%) were men and 35 (42%) were women. Gender-wise distribution of patients reporting ADRs has been tabulated in Table 2.

Table 3: Gender-wise distribution of patientsreporting ADRs in different studies.

Study	Male	Female
Gupta A. et al.[7] (2017)	108 (61.7%)	67 (38.3%)
Prajapati H. et al.[8] (2018)	65 (38%)	108 (62%)
Venkatasubbaiah M. et al.[9] (2018)	125 (49.2%)	129 (50.8%)
Misra D. et al.[10] (2019)	109 (60.6%)	71 (39.4%)
James J. et al.[11] (2020)	32 (40%)	48 (60%)

Average age of patients reporting ADRs in present study was 43.27±16.32 years. Mean age of men who reported ADRs was 46.14±15.86 years and that of women was 39.31±16.32 years. Most patients reporting ADRs were adults in age-group 19-40 years (39.76%) followed by age-group 41-60 years (37.35%). Only one patient who reported ADRs was in age-group above 80 years. Similarly in a study done by Prajapati H. et al., most patients reporting ADRs were in age-group 41-60 years (41.04%) and only one patient was in age-group above 80 years.[8] Venkatasubbaiah M. et al., reported that most ADRs were reported by adult patients of age between 18 and 65

years (71.26%) and this was significantly ($p<0.05$) higher than other age groups.[9] Misra D. et al., reported that most patients reporting ADRs were adults of age-group 31-45 years (42.8%).[10] In a study done by James J. et al., 60% of patients reporting ADRs were reported by patients in age-group 18-39 years.[11]

We found that GI system was most commonly affected (35%) and patients had symptoms like anorexia/dyspepsia/diarrhoea/nausea/vomiting/ oral ulcers/weight-loss/raised LFTs. Second most commonly affected system was skin with patients reporting rash & itching. CVS, excretory, genito-urinary and respiratory system were least involved with just one patient having ADRs of each system respectively. Gupta A et al., in their study reported that most ADRs were of skin and appendages (26.04%) followed by gastrointestinal disorders (24.3%).[7] Study by Prajapati H. et al., found that in most patients reporting ADRs primarily gastrointestinal system was involved, followed by nervous system.[8] Venkatasubbaiah M. et al., in their study found that most commonly Gastro-Intestinal (GI) system was affected followed by skin and central nervous system (CNS).[9] Misra D. et al., found that most common ADRs were from dermatological system involving skin followed by GI system.[10] In a study done by James J. et al., dermatological system had most ADRs followed by CNS and GI system.[11]

In our study 98% cases had non-serious ADRs and only 2% had serious ADRs and were recovering. At the last follow-up 65% patients had completely recovered and 35% were recovering. According to WHO causality assessment scale 48% cases were possible, 46% were probable/likely and 6% were unlikely. Causality assessment play a key role in relating the occurrence of ADRs due to drugs and other concurrent factors involved. This is turn is essential for maximum therapeutic benefit, patient safety and well-being through necessary changes to the label as deemed fit by the central licensing authority i.e., through drug controller general of India.

5. Conclusion

PvPI is leading great way for patient safety through prompt and spontaneous reporting of ADRs through various digital modes of reporting. AMCs network spread all across the country provide robust platform for pharmacovigilance to accomplish patient safety goals. We must promote sensitization programmes for health care professionals as well as general public to promote ADR reporting.

6. Acknowledgement

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7. Conflict of Interest

The authors declare no relevant conflicts of interest.

8. Source of Funding

None.

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