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ANALYSIS OF ADVERSE DRUG REACTIONS REPORTED BY UNDERGRADUATE MBBS STUDENTS AS A PART OF TEACHING PROGRAMME IN A MEDICAL COLLEGE AT DEHRADUN.

Pharmacology

Dr. Shalu Bawa Assistant Professor, Department of Pharmacology, SGRRIM&HS, Patel Nagar, Dehradun.

Dr. Mirza Atif Beg Associate Professor, Department of Pharmacology, SGRRIM&HS, Patel Nagar, Dehradun.

Dr. Shaktibala Dutta Professor, Department of Pharmacology, SGRRIM&HS, Patel Nagar, Dehradun.

Dr. Upender Kumar JR-III, Department of Pharmacology, SGRRIM&HS, Patel Nagar, Dehradun.

ABSTRACT

Objectives: Under-reporting of Adverse drug reactions(ADRs) is very common and one of the reasons could be the lack of awareness. Keeping this in mind, ADR monitoring was included in 2nd professional MBBS curriculum to develop awareness regarding ADR reporting.

Methods: Students were sensitized for ADR monitoring, and briefed about filling ADR reporting form and WHO causality assessment scale. The filled ADR forms were analysed in the department of Pharmacology.

Results: 572 ADRs were reported. 602 drugs were identified as culprit drugs, 312(51.83%) Antimicrobials, 128(21.27%) Analgesics, 49(8.14%) CNS drugs, 29(4.81%) GIT drugs, 25(4.15%) Multivitamins, 23(3.82%) Antihypertensives, 18(2.99%) Antidiabetics and drugs affecting blood system each. 560(97.91%) ADRs were non serious and 12(2.09%) were serious. 505(88.02%) ADRs were probable, 65(11.36%) possible and 2(0.35%) certain.

Conclusion: ADR monitoring was included in MBBS curriculum to create awareness amongst medical students, as they are the future prescribers.

KEYWORDS

Adverse drug reactions, Underreporting, Undergraduate medical students.

Introduction:

Adverse drug reaction (ADR) is a noxious, unintended and undesirable effect that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis and treatment (1). ADR is associated with significantly prolonged length of hospital stay, increased economic burden and almost 2-fold increased death. An ADR contributes to overall health care cost by increasing morbidity and even mortality in severe cases (2). Adverse drug reactions (ADRs) have been reported to be among leading causes of morbidity and mortality (3). It is estimated that approximately 2.9–5.6% of all hospital admissions are caused by ADRs and as many as 35% of hospitalized patients experience an ADR during their hospital stay (4). The spontaneous reporting of ADRs is considered as the foundation of post marketing surveillance of drug safety (5-7). Under-reporting of adverse drug reactions (ADRs) is very common and is estimated to be only 6–10% of all the ADRs that are reported (8). This reporting of ADRs is not appreciated enough by the health care professionals, thus leading to poor number of ADRs being reported in our country leading to delay in achieving the goals of pharmacovigillance (9). One of the reasons could be the lack of awareness regarding ADRs and their reporting in medical and paramedical professionals. Keeping this in mind, the identification, collection and reporting of ADRs has been included in the teaching curriculum of 2nd year MBBS students in Shri Guru Ram Rai Institute of Medical and Health Sciences (SGRRIM & HS), Dehradun.

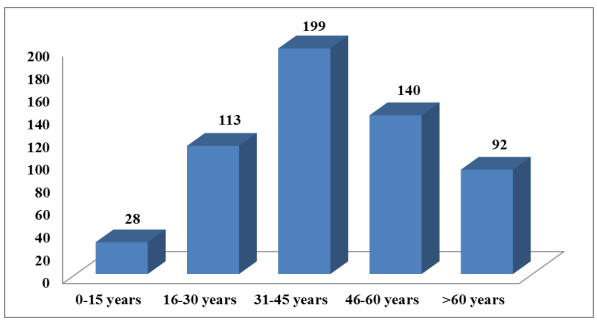
Material and Methods:

The present study was an observational study, conducted by department of Pharmacology, SGRRIM & HS, Dehradun for a period of 2 years from January 2015 to December 2016. ADR reporting was introduced in the curricullum of 2nd year MBBS students in which we taught and sensitized the 2nd year MBBS students about Adverse drug reactions (ADRs) and the role of pharmacovigilance through theory and practical class teaching. In the theory classes, we taught them about the definition, the types and the treatment modalities for various types of ADRs. During the practical classes, the importance was laid on filling of suspected ADR reporting form, and the students were briefed about WHO and Naranjo Causality Assessment Scales. A one week training program was organized by the department of Pharmacology during which the 2nd year MBBS students in 5th and 6th semesters were taken to different wards and OPDs of the hospital . The technique of history taking and identification of ADRs was taught to them. The students were divided in various groups and were provided ADR reporting forms along with WHO causality form. They carried their text books in the hospital and enquired the patients about the medicines being prescribed to them. Then after referring to their books, they would ask if the patients were experiencing any undesirable effect/ADR with the prescribed drugs. Once student identified an ADR, he/she would mention the details about it in the ADR reporting form.The filled ADR form along with the WHO causality fom were then submitted in the department of Pharmacology. The forms were assessed and analysed in the department of Pharmacology. After the entire exercise was over, students presented the ADR reports in the department in presence of all the faculty members and postgraduate students, where ADRs, their causes, and how they can be minimized or prevented were briefly discussed with students.

Results:

A total of 572 ADR reports were collected by 2nd MBBS students. The mean age of the patients was 43.1± 0.71(Mean ±SEM). In the present study there were 331(57.86%) male patients and 241(42.13%) female patients. The male:female ratio was 1.37:1. Patients were distributed according to their age group, 199(34.80%) patients were in 31-45 years, 140(24.48%) in 46-60 years, 113(19.75%) in 16-30 years, 92(16.08%) in > 60 years and 28(4.89%) in 0-15 year age group respectively (Figure 1).

Figure 1: Age wise distribution of patients



ADRs Reports were grouped according to various systems.

205(35.84%) ADRs were reported from Gastrointestinal (GI) system, followed by 156(27.27%) related to Central Nervous System(CNS), 110(19.23%) from Skin, 19(3.32%) from Haemotological system, 18(3.16%) from Genitourinary, 15(2.62%) from Endocrine, 13(2.27%) each related to Musculoskeletal and Respiratory, 9(1.57%) each from Cardiovascular System(CVS) and Eye and 5(0.88%) reports were in others category(Table 1).

Table1: System wise ADRs

System	Number (%age)
Gastrointestinal	205(35.84%)
CNS	156(27.27%)
Skin	110(19.23%)
Bleeding	19(3.32%)
Genitourinary	18(3.16%)
Endocrine	15(2.62%)
Musculoskeletal	13(2.27%)
Respiratory	13(2.27%)
Cardiovascular	9(1.57%)
Eye	9(1.57%)
Others	5(0.88%)

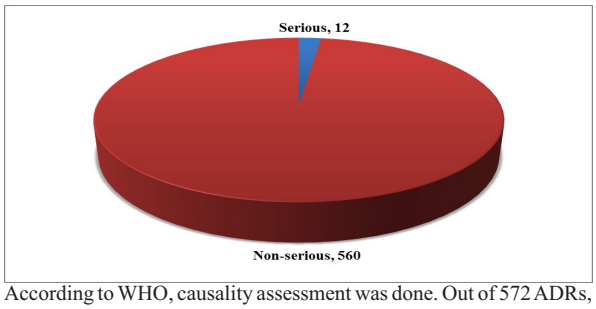
A total of 602 drugs were identified as culprit drugs for the reactions. 312(51.83%) Antimicrobials were leading drugs followed by 128(21.27%) Analgesics, 49(8.14%) CNS drugs, 29(4.81%) GIT drugs, 25(4.15%) Multivitamins, 23(3.82%) Antihypertensives, 18(2.99%) Antidiabetics and drugs affecting blood system each (Table 2).

Table 2: Drugs causing ADRs

Drug class	Number (% age)
Antimicrobials	312 (51.83%)
Analgesics	128 (21.27%)
CNS drugs	49 (8.14%)
GIT drugs	29 (4.81%)
Multivitamins	25 (4.15%)
Antihypertensives	23 (3.82%)
Antidiabetics	18 (2.99%)
Drugs affecting blood system	18 (2.99%)

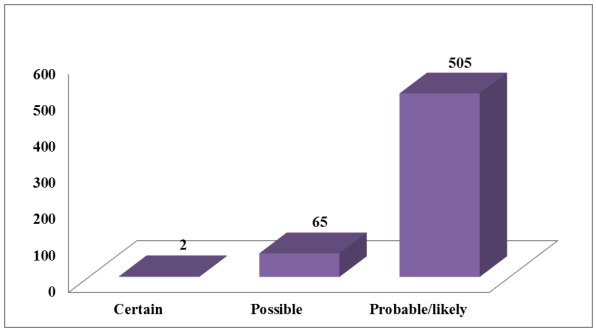
Out of 572 reactions, 560(97.91%) were non serious and 12(2.09%) reactions were reported to be serious (Figure 2).

Figure 2: Serious vs Nonserious ADRs



According to WHO, causality assessment was done. Out of 572 ADRs, 505(88.02%) were probable reactions followed by 65(11.36%) possible reactions and 2(0.35%) certain reactions (Figure 3).

Figure 3:WHO Causality Assessment Scale



Discussion:

The present study was an observational study of ADRs, which were collected and reported by the 2nd professional MBBS students between January 2015 to December 2016.

A total of 572 ADR reports were collected with a mean age of 43.1±0.71 years. This was similar to another study (9). There were more male patients as compared to females which was similar to previous studies (9, 10), indicating that male patients are more vocal in complaining ADRs than females.

Majority of the patients were in 31-45 year age group which was in collaboration with few earlier studies (11, 12) but was in contrast to other studies (10, 13). Majority of the ADRs belonged to Gastrointestinal system which included nausea, vomiting, abdominal pain and constipation. This finding was similar to earlier study (14) but in contrast to another previous study(15). Of the various classes of drugs implicated in causing ADRs, antimicrobials were the culprit drugs in 51.83% cases. This finding was similar to previous study (9). This was followed by analgesics which were the offending drugs in 21.27% cases. Our findings were consistent with an earlier study conducted by Roy K et al (15), which showed that the most common drug class implicated in ADRs was anti-microbials followed by analgesics. According to WHO causality assessment scale, 505(88.28%) ADRs were probable. This finding was similar to previos studies, where also most of the ADRs belonged to probable category (16, 17).

Since underreporting of ADRs is a major problem associated with the Pharmacovigilance Program of India (PvPI), as seen in previous studies (18, 19), the present study was attempted to teach MBBS 2nd professional students about the identification and reporting of ADRs which would in turn enhance their clinical skills. Since medical students are the future prescribers, such knowledge and training should be imparted to them during their undergraduate course.

Study limitation: In this study, the cases were not followed up by the students hence we could not get entire information regarding the outcome of ADRs.

Conclusion:

ADR reporting should be an ongoing and continuous process. Considering the need to create awareness and to promote the reporting of ADRs, steps must be taken to conduct sensitization programs amongst medical students who will be the future of our health care system.

References:

1. Vora MK, Narendra P. P, Vikas GD, Manish J. B, Tripathi CB. Knowledge of Adverse Drug Reactions and Pharmacovigilance Activity Among The Undergraduate Medical Students Of Gujarat. International Journal of Pharmaceutical Sciences and Research 2012;3(5):1-9.
2. Dhikav V, Singh S, Anand K S. Adverse drug reaction monitoring in India JIACM 2004; 5:27-33.
3. Singh A, Bhatt P. Comparative evaluation of adverse drug reaction reporting forms for introduction of a spontaneous generic ADR form J Pharmacol Pharmacotherapeutics 2012 ;3(3):228–232.
4. DeVries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: A systematic review QualSaf Health Care 2008;17:216–23.
5. Rishi RK, Patel RK, Bhandari A. Under-reporting of ADRs by medical practitioners in India - Results of pilot study.AdvPharmacoepidem Drug Safety 2012;1:1–3.
6. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2009;32:19–31.
7. Nichols V, Thériault-Dubé I, Touzin J, Delisle JF, Lebel D, Bussieres JF, et al. Risk perception and reasons for noncompliance in pharmacovigilance: a qualitative study conducted in Canada. Drug Saf. 2009;32:579–90.
8. Swapnil B. K, Nitin D. P. International Journal of Biomedical Research 2016; 7(5): 295-296.
9. Gupta A, Kaur A, Shukla P, Chhabra H. Adverse Drug Reactions pattern in a tertiary level teaching hospital: A Retrospective Study Journal of Pharmacy Practice 2017;10(1):27-31.
10. Pathak AK, Kumar M, Dokania S, Mohan L, Dikhit H. Retrospective Analysis Adverse Drug Reactions in a Tertiary Care Teaching Hospital Journal of Clinical and Diagnostic Research2016;10(8):1-4.
11. Dang A, Bhandare P. N. The Profile of Voluntary Reported Adverse Drug Reactions at a Tertiary Care Hospital: A Fifteen Month Prospective Study2012;6 (9):1504 – 9.
12. Baniasadi S, Fahimi F, Shalviri G, Developing an adverse drug reaction reporting system at a teaching hospital. Basic Clin Pharmacol Toxicol2008;102(4):408-11.
13. Santosh KC, Tragulpiankit P, Gorsanan S, Edwards R. BMC Pharmacology and Toxicology2013;14(16):1-7.
14. Gor AP, Desai S.V. 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. Roy K, Divya S, Nadig P, Prakash B. Monitoring and analysis of adverse drug reactions in a private tertiary care teaching hospital. Asian J Pharm Clini Res. 2015;8(2):335.
16. Bharathi AT, Sivasankari N, Rajeswari.MS, Sreelekha B. Retrospective Study On Adverse Drug Reaction In A Tertiary Care Hospital. Int J Pharm Bio Sci 2016;7(4): 294 – 298.

17. 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.
18. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: knowledge, attitude and practices of medical students and prescribers. Natl Med J India 2002;15:24-6.
19. Cosentino M, Leoni O, Banfi F, Leechini S, Frigo G. Attitudes to adverse drug reaction reporting by medical practitioners in a Northern Italian district. Pharmacol Res 1997; 35:85-8.